

Proposal Type: Informational Session

Date: March 2019 Society of Toxicology Meeting

Location: Baltimore, MD

Primary Endorser: Risk Assessment Specialty Section (RASS)

Secondary Endorser: Regulatory Safety and Evaluation Specialty Section (RSESS)

Title: Challenges and Opportunities Encountered With TSCA Reform: Working toward a Shared Vision for Product Safety

Chair: Darrell Boverhof, Ph.D. (The Dow Chemical Company)

Co-chair: Jeff Morris, Ph.D. (US EPA Office of Pollution Prevention and Toxics)

Abstract

The Lautenberg Chemical Safety Act (LCSA) was signed into law in June of 2016 to reform the Toxic Substance Control Act (TSCA). Its requirements provide many opportunities for improvements in how the science and information concerning the manufacture and use of chemicals is applied for ensuring safety regarding chemical exposures. While the scope covers many issues, the primary focus has been on how the U.S. EPA will carry out its mandate to evaluate both new and existing chemicals and manage those that pose an unreasonable risk. Specifically, EPA has been working on updating the pre-manufacture notification (PMN) process covered in Section 5, as well as developing processes to prioritize and evaluate existing chemicals in commerce under Section 6, in accordance with new science standards laid out in Section 26. Since the law became effective upon enactment, the Agency has had to meet many statutory deadlines in a short timeframe, e.g., finalize the prioritization and risk evaluation rules, complete scoping documents on the initial ten chemicals selected for risk evaluation, etc. In addition, the PMN process has been undergoing “fixes” in real time as attempts are made to navigate the statutory requirements for new chemicals without undue delays hindering innovation. More recently, discussions about data transparency for information used by the Agency in its regulatory decisions, has become a prominent part of the narrative. In addition, there are extensive efforts around how non-animal approaches can be used to fill data and information needs. There are both challenges and opportunities that must be addressed. Each of the three speakers provides the perspective of the groups they represent on how these challenges and opportunities can be addressed to achieve progress toward an improved chemicals management process in the US.

Chair: Darrell Boverhof, Ph.D. (The Dow Chemical Company) 10-minutes: Introduction

Speaker #1: Jeff Morris, Ph.D. (US EPA Office of Pollution Prevention and Toxics) – 20 minutes

Title: “EPA’s Progress on TSCA Implementation”

Abstract: This presentation highlights the EPA’s progress in implementing TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. These highlights will include key regulations, guidance documents, and activities completed in accord with the TSCA amendments, as

well as implementation actions and activities to be continued or initiated over the next year. Also presented will be a description of the issues raised in implementing the Lautenberg Act's provisions for new and existing chemicals, and how the EPA is addressing those issues.

Speaker #2: Mike Walls (American Chemistry Council) – 20 minutes

Title: "Perspectives on TSCA Implementation"

Abstract:

The TSCA amendments set the stage for the EPA to carry out their mandate to evaluate both new and existing chemicals in accordance with new scientific standards which include use of best available science and weight of the scientific evidence. Efficient evaluation of new chemicals remains critical to the ability to innovate. For existing chemicals, the key framework rules developed by EPA have established a foundation for process, and EPA activity surrounding the first ten chemicals selected for risk evaluation provides us with further valuable information for future risk evaluations of high priority substances. Opportunities for continued stakeholder engagement are a priority for success.

Speaker #3: Kristie Sullivan, M.P.H. (Physicians Committee for Responsible Medicine) – 20 minutes

Title: "TSCA Implementation: A Focus on New Approach Methodologies"

Abstract:

With a requirement for EPA and submitters to consider and use testing approaches not reliant on vertebrate animals whenever requesting or generating new information, the revisions to TSCA provide a framework for implementation of the National Academy of Sciences report *Toxicity Testing in the 21st Century: A vision and a strategy*. A lack of standard testing requirements represents an opportunity to implement flexible, responsive tiered testing frameworks to gather information the Agency needs to evaluate chemical safety outside of the "check box." EPA has released a strategy outlining how it will work to reduce and replace animal tests within its regulatory jurisdiction. It has also begun accepting New Approach Methodologies (NAMs) in place of, for example, the Local Lymph Node Assay. For continued progress it is essential that resources are dedicated to continuing scientific development such that the Adverse Outcome Pathway framework can serve as a source of potential new methods for toxicity assessment as well as a basis for supporting the validity of NAMs, overcoming some of the challenges with traditional validation. This presentation will offer a look at how policies and guidance enacted so far relate to NAM implementation, highlight opportunities for stakeholder involvement and international cooperation, and suggest key recommendations for continued momentum in implementing 21st-century regulatory toxicology.

Audience Questions for Speaker(s) – 10 minutes

Message

From: Boverhof, Darrell (R) [RBoverhof@dow.com]
Sent: 2/13/2019 3:13:37 PM
To: Morris, Jeff [Morris.Jeff@epa.gov]; ksullivan@pcrm.org; Walls, Michael [Michael_Walls@americanchemistry.com]
CC: Budinsky, Robert (R) [RABudinsky@dow.com]; Hartigan, Suzanne [Suzanne_Hartigan@americanchemistry.com]
Subject: RE: Scientific Session Alert from SOT
Attachments: 2019 SOT LCSA Informational Session Abstract -Final- 8-8-2018.docx

All,

A reminder of our meeting today.

My proposal for this meeting:

Wed Feb 13-

Discuss the abstract and provide bullet points on planned points for discussion for each speaker

As we go through these- we as a team can ask questions and make requests for additional points in an effort to coordinate and round out the discussion

The goal is to come with some refreshed thoughts and then ensure our focus is somewhat coordinated with respect to key issues topics.

For me- my goal is to provide important introductory remarks that set the landscape for the topic and the sessions that follow.

Looking forward to discussing/refreshing on this topic.

Best regards,
Darrell

From: Boverhof, Darrell (R)
Sent: Thursday, January 31, 2019 9:14 AM
To: 'Morris, Jeff' <Morris.Jeff@epa.gov>; 'Kristie Sullivan' <KSullivan@pcrm.org>; 'Walls, Michael' <Michael_Walls@americanchemistry.com>
Cc: Budinsky, Robert (R) <RABudinsky@dow.com>; 'Hartigan, Suzanne' <Suzanne_Hartigan@americanchemistry.com>; Boverhof, Darrell (R) <RBoverhof@dow.com>
Subject: RE: Scientific Session Alert from SOT
Importance: High

Folks,

Based on the doodle poll you all responded to- I have now identified two dates that should work for our discussions.

Wednesday Feb 13 from 1-2pm EST

and

Wednesday Feb 27 from 3-4pm EST

I will send out meeting notices with WebEx links for these calls.

My proposal for the meetings:

Wed Feb 13-

Discuss the abstract and provide bullet points on planned points for discussion for each speaker

As we go through these- we as a team can ask questions and make requests for additional points in an effort to coordinate and round out the discussion

The goal is to come with some refreshed thoughts and then ensure our focus is somewhat coordinated with respect to key issues topics.

For me- my goal is to provide important introductory remarks that set the landscape for the topic and the sessions that follow.

Wed Feb 27- Plan will be to share more specifics on our talks (near final) including slides. I hope this will be near final with some additional thoughts shared. This will be less than 2 weeks in advance of our session.

Meeting notices to follow- looking forward to our discussions!

If you have additional thoughts on the approach leading up to these meetings- please let me know!

Darrell

Darrell R. Boverhof, Ph.D.

Director - Toxicology & Environmental Research and Consulting (TERC)

The Dow Chemical Company

1803 Building, Midland MI, 48674, USA

(989)638-7641

<mailto:RBoverhof@dow.com>



WORLDWIDE PARTNER

From: Boverhof, Darrell (R)

Sent: Wednesday, January 16, 2019 7:23 PM

To: 'Morris, Jeff' <Morris.Jeff@epa.gov>; 'Kristie Sullivan' <KSullivan@pcrm.org>; 'Walls, Michael' <Michael_Walls@americanchemistry.com>

Cc: Budinsky, Robert (R) <RABudinsky@dow.com>; Hartigan, Suzanne <Suzanne_Hartigan@americanchemistry.com>

Subject: Scientific Session Alert from SOT

Importance: High

Dear Colleagues,

We are less than two months away from SOT and our session on:

Challenges and Opportunities Encountered with TSCA Reform: Working toward a Shared Vision for Product Safety.

Our session is set for Tuesday March 12 from 11 AM to 12:20 PM in CC Room 314

As indicated last year during preparation of abstracts- I think it would be useful for us to meet as a group a couple of times prior to our session. This will ensure we are all on the same page with respect to the content and flow for the session and we can adjust our approach to ensure maximal impact.

As a refresher- the abstracts we submitted are attached.

See this link for a doodle poll with several dates noted between now and the end of February. Apologies for the large poll but I want to give flexibility. It is narrowed to 1 hour sessions on Tuesday, Wed and Thursday afternoons.

<https://doodle.com/poll/dsvcmzkn67vk43t9>

My goal would be to have our first meeting in the last week of Jan/first week of Feb, and then a second meeting in the 3rd or 4th week of Feb.

Thanks in advance for filling out this poll by COB this Friday- January 18- a quick turnaround will allow us to lock in dates before our calendars get consumed with other meetings.

Looking forward to a good discussion to further shape this session!

Best regards,
Darrell

Darrell R. Boverhof, Ph.D.
Director - Toxicology & Environmental Research and Consulting (TERC)
The Dow Chemical Company
1803 Building, Midland MI, 48674, USA
(989)638-7641
<mailto:RBoverhof@dow.com>



From: David Rosse [<mailto:davidr@toxicology.org>]
Sent: Thursday, September 27, 2018 12:17 PM
To: Boverhof, Darrell (R) <RBoverhof@dow.com>; Morris.Jeff@epa.gov
Subject: Scientific Session Alert from SOT

This email originated from outside of the organization.

DATE: September 27, 2018
TO: 2019 SOT Annual Meeting Session Chairpersons
FROM: Ron Hines, Chairperson, Scientific Program Committee

It is a great pleasure to inform you of the final acceptance of your Informational Session entitled **Challenges and Opportunities Encountered with TSCA Reform: Working toward a Shared Vision for Product Safety** for the Society of Toxicology (SOT) Annual Meeting in Baltimore, Maryland, being held from March 10–14, 2019. Your session has been programmed to take place on Tuesday, March 12, 2019 from 11:00 AM to 12:20 PM in Room 314 of the Baltimore Convention Center. Please communicate these session details to your presenters.

Please also remind any nonmember speakers you may have in your session that they will receive complimentary registration to attend the Annual Meeting, and that they should not complete an Annual Meeting registration form. SOT Headquarters will handle all nonmember speaker registrations. SOT will contact nonmember speakers approved for full-funding support by the end of October with housing and travel

logistical information. As a reminder, SOT members are not eligible for any type of travel or registration funding.

In compliance with the SOT Conflict of Interest policy, please advise your speakers that a disclosure slide must be included as the second slide of every presentation, or in the lower corner of the introduction slide.

As we approach the Annual Meeting in March, if any of your speakers find they are unable to attend the Annual Meeting, it is up to the speaker to notify the session chairs immediately, so necessary replacement speaker arrangements can be made. SOT headquarters (David Rossé: davidr@toxicology.org) must be copied on these arrangements.

If you have any questions about this session, please feel free to contact David via email or telephone at 703.438.3115. Thank you for your assistance and I look forward to seeing you in Baltimore this March!

Annual Meeting website: <https://www.toxicology.org/events/am/AM2019/index.asp>

Thank you.

Ron Hines

Chair: Darrell Boverhof
Co-Chair: Jeffery Morris

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Sent: 1/17/2019 12:22:51 AM
To: Morris, Jeff [Morris.Jeff@epa.gov]; ksullivan@pcrm.org; Walls, Michael [Michael_Walls@americanchemistry.com]
CC: Budinsky, Robert (R) [RABudinsky@dow.com]; Hartigan, Suzanne [Suzanne_Hartigan@americanchemistry.com]
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FROM: Ron Hines, Chairperson, Scientific Program Committee

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Audience Questions for Speaker(s) – 10 minutes

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 10/26/2018 10:13:34 PM
To: Eve C. Gartner, Esquire [egartner@earthjustice.org]; Karyn M. Schmidt, Esquire [karyn_schmidt@americanchemistry.com]; Rose Passarella, Ph.D., J.D. [rose.passarella@intertek.com]; Morris, Jeff [Morris.Jeff@epa.gov]; Sally Bradley [sally.bradley@chemicalwatch.com]; Edwin C. Bisinger, Jr., Ph.D. [Edwin.Bisinger@akzonobel.com]
Subject: Chemical Watch US 2018 Summit -TSCA
Attachments: 00254513.docx

Colleagues,

Here are questions I could ask in the second part of our discussion. Happy to discuss.

Have great weekend.

Lynn

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson
Sent: Sunday, October 21, 2018 9:39 PM
To: Eve C. Gartner, Esquire; Karyn M. Schmidt, Esquire; Rose Passarella, Ph.D., J.D.; Jeffery T. Morris, Ph.D.; Sally Bradley
Subject: Chemical Watch US 2018 Summit -TSCA

Colleagues,

This supplements our call on Friday afternoon. As we discussed, we agreed that the discussion would flow better and perhaps invite more audience interaction and attention if we do things a bit differently than the program now suggests. The TSCA block begins at 9:00 and concludes at 11:50. There is a 20 minute break in this block. After discussion, we would like to proceed as follows:

9:00-9:30 Bergeson provides a broad overview of TSCA at 2, noting EPA's implementation milestones and providing commentary along the way. I circulated my slides last week.

As we discussed, we suggest as an alternative that each panelist then give an individual presentation that would be structured to respond to these questions:

1. Did Lautenberg do a good job in addressing TSCA's deficiencies? Whatever your answer, please explain your response.
2. Hind sight is always 20/20. If you could do anything over again in Lautenberg or EPA's implementation of it, what would that be?
3. In terms of EPA's implementation of Lautenberg, what are EPA's successes, near misses, and actual misses, if any?
4. What do you like most about EPA's implementation of Lautenberg?
5. What do you like least?
6. If there is a hearing in the House early next year on EPA's implementation of TSCA, what do you expect the issues would include?

7. Would TSCA implementation have been better served with the help of a FACA?

The reason we are thinking that responding to questions is preferable is it allows a better platform for the perspective of each speaker to emerge. We all agreed that we did not want to do another “TSCA tutorial” as there have been many programs and webinars over the past two years that fill that bill. In addition, we think the audience is typically fairly sophisticated and might appreciate hearing the unique views of each speaker and in that context address key issues, challenges, and opportunities occasioned by Lautenberg and EPA’s implementation of it.

Here is the first half of the TSCA session:

Bergeson overview

9:30-9:45	Jeff
9:45-10:00	Eve
10:00-10:15	Karyn
10:15-10:30	Rose (this programming assumes no additional speaker)

COFFER BREAK

The second portion of the TSCA session would include all speakers on stage where we would ask each other questions derived from the presentations given before the break and take questions from the audience. That leaves from 10:50-11:50 (one hour) to engage in a spirited directed conversation about all aspects of TSCA, EPA’s implementation, the litigations, and related topics.

Last year, there were a fair number of questions from the audience. I see no difficulty in filling 60 minutes. I also volunteered to prepare questions to get the part started, and will do so by Tuesday.

Thoughts appreciated.

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
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Chemical Watch Regulatory Summit 2018

TSCA at 2

Questions for the Panel

October 31, 2018

Jeff Morris

- New Toxic Substances Control Act (TSCA) requires that the U.S. Environmental Protection Agency (EPA) establish the Science Advisory Committee on Chemicals (SACC) that is required to meet at least every two years. The SACC was established, but EPA has reopened the nomination process since then. What is the status of the SACC and when can we expect to see it meet?
- The Office of Pollution Prevention and Toxics (OPPT) has initiated a process to reorganize itself to meet better the demands of new TSCA. What is the status of the reorganization?
- According to the recently published Fall Regulatory Agenda, EPA will be proposing revisions to the Chemical Data Reporting (CDR) rule. Can you give us any insights into the kinds of changes that EPA might be contemplating for this proposed rule?
- EPA is working on several risk evaluations and the results will not be available for some time according to the TSCA deadlines. Without telling us anything you cannot, what observations can you make about the risk evaluation process and what OPPT is learning and wrestling with at this point?

All but Jeff

- New TSCA Section 4 includes several important changes in EPA's testing authority. While OPPT has been busy implementing other parts of the law, it has not used Section 4 to require testing since the new law was enacted. What is your reaction to this situation and are you surprised? Do you have any suggestions or advice for Jeff in this regard?
 - **Jeff**, what can you tell us about EPA plans and timing for using Section 4?
- The fees rule was published on October 17, 2018, and it will serve to provide much needed additional resources to EPA to meet the new requirements of the law. What is your reaction to the final rule and do you think EPA did a good job of striking an appropriate balance in obtaining the resources needed by EPA and in allocating industry's fee burdens?

- The Inventory notification reporting process is working its way to conclusion and seems to indicate that about 40,000 of the 85,000 chemicals on the TSCA Inventory are currently in commerce. Were you surprised by this result? Would you like to see OPPT prepare a non-confidential business information (CBI) report analyzing the results and explaining to the public what it found regarding the chemicals that are in commerce at this point in time? Could such a report also offer some characterization of the chemicals that are not currently being made and used? For example, has there been a discernable shift away from persistent, bioaccumulative, and toxic (PBT) chemicals since the original Inventory was created? If you like the idea, feel free to offer suggestions for other questions that EPA might consider.
 - **Jeff:** What are your reactions to the idea and to the points made by other panelists?
- I know that each of you has different views regarding EPA's implementation of Section 5. After considerable initial disruption and delays, the process seems to be settling down, at least for now. What do you see as the key issues and problems going forward and what do you think EPA has done well in getting to this point?
- EPA recently released its *Working Approach to Identifying Potential Candidate Chemicals for Prioritization*. What was your general reaction to EPA's approach, particularly with regard to the near-term elements? The approach involves relying on existing understanding and approaches such as the 2014 Work Plan chemicals, Safer Chemicals Ingredients List (SCIL), and existing reviews such as those developed under the Organization for Economic Cooperation and Development's (OECD) Screening Information Data Set/High Production Volume (SIDS HPV) program and the Chemical Assessment and Management Program (ChAMP) effort. Good idea or not?
 - **Jeff:** Anything to add?
- Anything on CBI?
- As part of EPA's prioritization process under Section 6, EPA has opened dockets for the TSCA Work Plan chemicals. Based on limited experience with the chemicals currently engaged in Section 6 risk evaluation, it is difficult for manufacturers to engage the full value chain to prepare to work with EPA. Not all of these chemicals will be in the next round of Section 6 screening/prioritization and some value chain stakeholders will not wish to engage unless or until they believe their chemical of concern is truly up for review with EPA. Will those chemicals not prioritized this year still have open dockets past December 2019?

- At the end of the risk evaluation process, in situations in which certain use applications are the focus of EPA concern, the onus is on the chemical manufacturer to advocate on risk management proposals -- even if those applications are not related to the manufacturers' workplace practices, which again begs the question on how to best engage the value chain. Will EPA be doing more to inform/educate chemical users? (Perhaps a similar question to Karyn on what ACC is doing in this regard?)
- Other questions?

Message

From: Mark Duvall [MDuvall@bdlaw.com]
Sent: 2/23/2018 2:04:43 PM
To: Brozena, Sarah [Sarah_Brozena@americanchemistry.com]; Morris, Jeff [Morris.Jeff@epa.gov]; Dekleva, Lynn A. [lynn-ann.dekleva-1@dupont.com]
Subject: RE: Global Chem session organizing call:
Attachments: Conditions of Use Under TSCA Sections 5 and 6 - 2-23-18.PPTX

FYI, here is my final presentation.

Sarah, I think I can get through this fairly quickly.

Mark Duvall
Principal

BEVERIDGE & DIAMOND, P.C.
T +1.202.789.6090 F +1.202.789.6190 MDuvall@bdlaw.com

From: Mark Duvall
Sent: Thursday, February 22, 2018 11:25 AM
To: 'Brozena, Sarah'; Morris.jeff@Epa.gov; Dekleva, Lynn A.
Subject: RE: Global Chem session organizing call:

Colleagues, FYI, here is the current draft of my presentation.

Mark Duvall
Principal

BEVERIDGE & DIAMOND, P.C.
T +1.202.789.6090 F +1.202.789.6190 MDuvall@bdlaw.com

From: Brozena, Sarah [mailto:Sarah_Brozena@americanchemistry.com]
Sent: Monday, January 22, 2018 1:30 PM
To: Morris.jeff@Epa.gov; Dekleva, Lynn A.; Mark Duvall
Subject: Global Chem session organizing call: please reply today

TO: Jeff Morris, EPA
Lynn Dekleva, Dupont
Mark Duvall, Beveridge & Diamond
FROM: Sarah Brozena, ACC
RE: Organizing call for March 1 GlobalChem session
DATE: January 22, 2018

Good afternoon.

Thanks for volunteering to speak at GlobalChem this year. As you know, GlobalChem is ACC's annual conference on chemical management issues. It's taking place this year February 28-March 2 at the OMNI Shoreham Hotel in Washington, DC. This year, GlobalChem's theme relates to implementation of TSCA.

I'm the moderator of the GlobalChem conference session on Thursday, March 1 at which you've agreed to speak, titled "Year One: Lessons Learned and Keys to Moving Ahead." This session will begin at 10 a.m. that day. Attached is the current draft agenda for the whole of GlobalChem. This session can be found on page 5 of the draft agenda.

I'd like to schedule a one-hour max conference call, preferably sometime this week, to get a sense of which topics in this session each of you would like to cover. Here are some dates and times that would work for me:

Tuesday, Jan. 23 – sometime between 1 p.m. and 4 p.m.

Wednesday, Jan. 24 – sometime between 10 a.m. and 4 p.m.

Thursday, Jan. 25 – sometime between 9 a.m. and 12 p.m.

Please let me know today of your availability on these three days during these timeslots. If none of these times works, let me know when you would be available, preferably no later than sometime next week. After I sort out the best time, I'll send you a follow-up email and then an Outlook invitation with call in information.

Thanks,
Sarah

Sarah H. Brozena

Senior Director, Regulatory & Technical Affairs

American Chemistry Council

700 Second St., NE

Washington, DC 20002

202-249-6403

Sarah_Brozena@americanchemistry.com

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Message

From: Mark Duvall [MDuvall@bdlaw.com]
Sent: 2/22/2018 4:25:13 PM
To: Brozena, Sarah [Sarah_Brozena@americanchemistry.com]; Morris, Jeff [Morris.Jeff@epa.gov]; Dekleva, Lynn A. [lynn-ann.dekleva-1@dupont.com]
Subject: RE: Global Chem session organizing call:
Attachments: Conditions of Use Under TSCA Sections 5 and 6 - 2-22-18.PPTX

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Mark Duvall
Principal

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T +1.202.789.6090 F +1.202.789.6190 MDuvall@bdlaw.com

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Lynn Dekleva, Dupont
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American Chemistry Council
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Washington, DC 20002
202-249-6403
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Message

From: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
Sent: 7/2/2019 1:49:40 PM
To: Richard E. Engler, Ph.D. [rengler@lawbc.com]
CC: lbergeson@lawbc.com; Heidi Brown Lewis [hlewis@lawbc.com]; Hanley, Mary [Hanley.Mary@epa.gov]; Bolen, Derrick [bolen.derrick@epa.gov]
Subject: Re: Webinar in July

Hi Rich. Yes, Please reach out to Alex's office on logistics. Thanks.

Jeff

Sent from my iPhone

On Jul 2, 2019, at 9:14 AM, Richard E. Engler, Ph.D. <rengler@lawbc.com> wrote:

Jeff:

I understand you will be on extended leave for the rest of the summer. Does this mean that Alex will be joining us on July 25 for the webinar?

Rich

RICHARD E. ENGLER, PH.D.
DIRECTOR OF CHEMISTRY
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

From: Morris, Jeff <Morris.Jeff@epa.gov>
Sent: Monday, June 10, 2019 11:15 AM
To: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Lynn L. Bergeson <lbergeson@lawbc.com>; Heidi Brown Lewis <hlewis@lawbc.com>; Henry, Tala <Henry.Tala@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>
Subject: RE: Webinar in July

Rich,

Thanks for the offer to participate. We will discuss within the office this week and get back with you soon.

All the best,

Jeff

From: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Sent: Friday, June 07, 2019 2:48 PM
To: Morris, Jeff <Morris.Jeff@epa.gov>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; lbergeson@lawbc.com; Heidi Brown Lewis <hlewis@lawbc.com>
Subject: Webinar in July

Jeff:

On July 25, Bergeson & Campbell, P.C. will be hosting a webinar to follow-up on topics discussed in the TSCA at 3 ELI workshop. The current working title of the webinar is **TSCA at 3: Overview With a Focus on Evolving New Chemical Policies and Practices**. The discussion will capture quickly key points from ELI conference and then pivot to Section 5 issues with a goal of identifying specific challenges and what stakeholders can do to avoid them.

B&C would be pleased if you could participate to discuss OPPT's views on these issues.

Please advise of your availability to join B&C for this webinar or if another day that week would be better for you.

Rich

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BERGESON & CAMPBELL PC
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T: 202-557-3808 | F: 202-557-3836 | lawbc.com

Message

From: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
Sent: 6/10/2019 3:14:34 PM
To: Richard E. Engler, Ph.D. [rengler@lawbc.com]
CC: Pierce, Alison [Pierce.Alison@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; lbergeson@lawbc.com; Heidi Brown Lewis [hlewis@lawbc.com]; Henry, Tala [Henry.Tala@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]
Subject: RE: Webinar in July

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Sent: Friday, June 07, 2019 2:48 PM
To: Morris, Jeff <Morris.Jeff@epa.gov>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; lbergeson@lawbc.com; Heidi Brown Lewis <hlewis@lawbc.com>
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B&C would be pleased if you could participate to discuss OPPT's views on these issues.

Please advise of your availability to join B&C for this webinar or if another day that week would be better for you.

Rich

RICHARD E. ENGLER, PH.D.
DIRECTOR OF CHEMISTRY
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

Message

From: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
Sent: 3/23/2019 11:51:23 AM
To: Kathleen M. Roberts [kroberts@lawbc.com]
CC: lbergeson@lawbc.com; Beck, Nancy [Beck.Nancy@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Tala Henry (Henry.Tala@epa.gov) [Henry.Tala@epa.gov]; Wormell, Lance [Wormell.Lance@epa.gov]; Ryan Schmit (schmit.ryan@epa.gov) [schmit.ryan@epa.gov]
Subject: RE: TSCA NCC - Letter on EPA Practice for SNUR rulemakings and White Paper - Consideration of 'Nonrisk' Versus 'Risk' Factors Under Toxic Substances Control Act Section 5

Kathleen,

Thank you very much for the letter and white paper from the New Chemicals Coalition. We will review the material and reach out to you if we have any questions or believe that follow-up with the NCC is needed.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

From: Kathleen M. Roberts <kroberts@lawbc.com>
Sent: Friday, March 22, 2019 3:59 PM
To: Morris, Jeff <Morris.Jeff@epa.gov>
Cc: lbergeson@lawbc.com; Beck, Nancy <Beck.Nancy@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>
Subject: TSCA NCC - Letter on EPA Practice for SNUR rulemakings and White Paper - Consideration of 'Nonrisk' Versus 'Risk' Factors Under Toxic Substances Control Act Section 5

Jeff:

Appended is a letter from the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) requesting a change in the current U.S. Environmental Protection Agency (EPA) practices regarding direct final rulemakings for Significant New Use Rule (SNUR) notices impacting multiple chemicals (document number 258856).

Also appended for your consideration is a white paper prepared by the TSCA NCC on the "Consideration of 'Nonrisk' Versus 'Risk' Factors Under Toxic Substances Control Act Section 5" (document number 252550).

If it would be helpful, we would be pleased to meet with you and your staff to discuss these documents further.

KATHLEEN M. ROBERTS
VICE PRESIDENT

B&C CONSORTIA MANAGEMENT LLC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037

T: 202-833-6581 | F: 202-557-3836 | bc-cm.com

Appointment

From: Boverhof, Darrell (R) [RBoverhof@dow.com]
Sent: 1/31/2019 2:20:20 PM
To: Morris, Jeff [Morris.Jeff@epa.gov]; ksullivan@pcrm.org; 'Walls, Michael' [Michael_Walls@americanchemistry.com]; Budinsky, Robert (R) [RABudinsky@dow.com]; Hartigan, Suzanne [Suzanne_Hartigan@americanchemistry.com]
Subject: SOT LCSA Session- Discussion 2
Attachments: 2019 SOT LCSA Informational Session Abstract -Final- 8-8-2018.docx
Location: WebEx

Start: 2/27/2019 8:00:00 PM
End: 2/27/2019 9:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Folks,

Based on the doodle poll you all responded to- I have now identified two dates that should work for our discussions.

Wednesday Feb 13 from 1-2pm EST
and
Wednesday Feb 27 from 3-4pm EST

I will send out meeting notices with WebEx links for these calls.

My proposal for the meetings:

Wed Feb 13-

Discuss the abstract and provide bullet points on planed points for discussion for each speaker

As we go through these- we as a team can ask questions and make requests for additional points in an effort to coordinate and round out the discussion

The goal is to come with some refreshed thoughts and then ensure our focus is somewhat coordinated with respect to key issues topics.

For me- my goal is to provide important introductory remarks that set the landscape for the topic and the sessions that follow.

Wed Feb 27- Plan will be to share more specifics on our talks (near final) including slides. I hope this will be near final with some additional thoughts shared. This will be less than 2 weeks in advance of our session.

Meeting notices to follow- looking forward to our discussions!

Darrell

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Proposal Type: Informational Session

Date: March 2019 Society of Toxicology Meeting

Location: Baltimore, MD

Primary Endorser: Risk Assessment Specialty Section (RASS)

Secondary Endorser: Regulatory Safety and Evaluation Specialty Section (RSESS)

Title: Challenges and Opportunities Encountered With TSCA Reform: Working toward a Shared Vision for Product Safety

Chair: Darrell Boverhof, Ph.D. (The Dow Chemical Company)

Co-chair: Jeff Morris, Ph.D. (US EPA Office of Pollution Prevention and Toxics)

Abstract

The Lautenberg Chemical Safety Act (LCSEA) was signed into law in June of 2016 to reform the Toxic Substance Control Act (TSCA). Its requirements provide many opportunities for improvements in how the science and information concerning the manufacture and use of chemicals is applied for ensuring safety regarding chemical exposures. While the scope covers many issues, the primary focus has been on how the U.S. EPA will carry out its mandate to evaluate both new and existing chemicals and manage those that pose an unreasonable risk. Specifically, EPA has been working on updating the pre-manufacture notification (PMN) process covered in Section 5, as well as developing processes to prioritize and evaluate existing chemicals in commerce under Section 6, in accordance with new science standards laid out in Section 26. Since the law became effective upon enactment, the Agency has had to meet many statutory deadlines in a short timeframe, e.g., finalize the prioritization and risk evaluation rules, complete scoping documents on the initial ten chemicals selected for risk evaluation, etc. In addition, the PMN process has been undergoing “fixes” in real time as attempts are made to navigate the statutory requirements for new chemicals without undue delays hindering innovation. More recently, discussions about data transparency for information used by the Agency in its regulatory decisions, has become a prominent part of the narrative. In addition, there are extensive efforts around how non-animal approaches can be used to fill data and information needs. There are both challenges and opportunities that must be addressed. Each of the three speakers provides the perspective of the groups they represent on how these challenges and opportunities can be addressed to achieve progress toward an improved chemicals management process in the US.

Chair: Darrell Boverhof, Ph.D. (The Dow Chemical Company) 10-minutes: Introduction

Speaker #1: Jeff Morris, Ph.D. (US EPA Office of Pollution Prevention and Toxics) – 20 minutes

Title: “EPA’s Progress on TSCA Implementation”

Abstract: This presentation highlights the EPA’s progress in implementing TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. These highlights will include key regulations, guidance documents, and activities completed in accord with the TSCA amendments, as

well as implementation actions and activities to be continued or initiated over the next year. Also presented will be a description of the issues raised in implementing the Lautenberg Act's provisions for new and existing chemicals, and how the EPA is addressing those issues.

Speaker #2: Mike Walls (American Chemistry Council) – 20 minutes

Title: "Perspectives on TSCA Implementation"

Abstract:

The TSCA amendments set the stage for the EPA to carry out their mandate to evaluate both new and existing chemicals in accordance with new scientific standards which include use of best available science and weight of the scientific evidence. Efficient evaluation of new chemicals remains critical to the ability to innovate. For existing chemicals, the key framework rules developed by EPA have established a foundation for process, and EPA activity surrounding the first ten chemicals selected for risk evaluation provides us with further valuable information for future risk evaluations of high priority substances. Opportunities for continued stakeholder engagement are a priority for success.

Speaker #3: Kristie Sullivan, M.P.H. (Physicians Committee for Responsible Medicine) – 20 minutes

Title: "TSCA Implementation: A Focus on New Approach Methodologies"

Abstract:

With a requirement for EPA and submitters to consider and use testing approaches not reliant on vertebrate animals whenever requesting or generating new information, the revisions to TSCA provide a framework for implementation of the National Academy of Sciences report *Toxicity Testing in the 21st Century: A vision and a strategy*. A lack of standard testing requirements represents an opportunity to implement flexible, responsive tiered testing frameworks to gather information the Agency needs to evaluate chemical safety outside of the "check box." EPA has released a strategy outlining how it will work to reduce and replace animal tests within its regulatory jurisdiction. It has also begun accepting New Approach Methodologies (NAMs) in place of, for example, the Local Lymph Node Assay. For continued progress it is essential that resources are dedicated to continuing scientific development such that the Adverse Outcome Pathway framework can serve as a source of potential new methods for toxicity assessment as well as a basis for supporting the validity of NAMs, overcoming some of the challenges with traditional validation. This presentation will offer a look at how policies and guidance enacted so far relate to NAM implementation, highlight opportunities for stakeholder involvement and international cooperation, and suggest key recommendations for continued momentum in implementing 21st-century regulatory toxicology.

Audience Questions for Speaker(s) – 10 minutes

Appointment

From: Boverhof, Darrell (R) [RBoverhof@dow.com]
Sent: 1/31/2019 2:18:59 PM
To: Morris, Jeff [Morris.Jeff@epa.gov]; ksullivan@pcrm.org; Walls, Michael [Michael_Walls@americanchemistry.com]; Budinsky, Robert (R) [RABudinsky@dow.com]; Hartigan, Suzanne [Suzanne_Hartigan@americanchemistry.com]
Subject: SOT LCSA session- Discussion 1
Attachments: 2019 SOT LCSA Informational Session Abstract -Final- 8-8-2018.docx
Location: WebEx

Start: 2/13/2019 6:00:00 PM
End: 2/13/2019 7:00:00 PM
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Recurrence: (none)

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Secondary Endorser: Regulatory Safety and Evaluation Specialty Section (RSESS)

Title: Challenges and Opportunities Encountered With TSCA Reform: Working toward a Shared Vision for Product Safety

Chair: Darrell Boverhof, Ph.D. (The Dow Chemical Company)

Co-chair: Jeff Morris, Ph.D. (US EPA Office of Pollution Prevention and Toxics)

Abstract

The Lautenberg Chemical Safety Act (LCSA) was signed into law in June of 2016 to reform the Toxic Substance Control Act (TSCA). Its requirements provide many opportunities for improvements in how the science and information concerning the manufacture and use of chemicals is applied for ensuring safety regarding chemical exposures. While the scope covers many issues, the primary focus has been on how the U.S. EPA will carry out its mandate to evaluate both new and existing chemicals and manage those that pose an unreasonable risk. Specifically, EPA has been working on updating the pre-manufacture notification (PMN) process covered in Section 5, as well as developing processes to prioritize and evaluate existing chemicals in commerce under Section 6, in accordance with new science standards laid out in Section 26. Since the law became effective upon enactment, the Agency has had to meet many statutory deadlines in a short timeframe, e.g., finalize the prioritization and risk evaluation rules, complete scoping documents on the initial ten chemicals selected for risk evaluation, etc. In addition, the PMN process has been undergoing “fixes” in real time as attempts are made to navigate the statutory requirements for new chemicals without undue delays hindering innovation. More recently, discussions about data transparency for information used by the Agency in its regulatory decisions, has become a prominent part of the narrative. In addition, there are extensive efforts around how non-animal approaches can be used to fill data and information needs. There are both challenges and opportunities that must be addressed. Each of the three speakers provides the perspective of the groups they represent on how these challenges and opportunities can be addressed to achieve progress toward an improved chemicals management process in the US.

Chair: Darrell Boverhof, Ph.D. (The Dow Chemical Company) 10-minutes: Introduction

Speaker #1: Jeff Morris, Ph.D. (US EPA Office of Pollution Prevention and Toxics) – 20 minutes

Title: “EPA’s Progress on TSCA Implementation”

Abstract: This presentation highlights the EPA’s progress in implementing TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. These highlights will include key regulations, guidance documents, and activities completed in accord with the TSCA amendments, as

well as implementation actions and activities to be continued or initiated over the next year. Also presented will be a description of the issues raised in implementing the Lautenberg Act's provisions for new and existing chemicals, and how the EPA is addressing those issues.

Speaker #2: Mike Walls (American Chemistry Council) – 20 minutes

Title: "Perspectives on TSCA Implementation"

Abstract:

The TSCA amendments set the stage for the EPA to carry out their mandate to evaluate both new and existing chemicals in accordance with new scientific standards which include use of best available science and weight of the scientific evidence. Efficient evaluation of new chemicals remains critical to the ability to innovate. For existing chemicals, the key framework rules developed by EPA have established a foundation for process, and EPA activity surrounding the first ten chemicals selected for risk evaluation provides us with further valuable information for future risk evaluations of high priority substances. Opportunities for continued stakeholder engagement are a priority for success.

Speaker #3: Kristie Sullivan, M.P.H. (Physicians Committee for Responsible Medicine) – 20 minutes

Title: "TSCA Implementation: A Focus on New Approach Methodologies"

Abstract:

With a requirement for EPA and submitters to consider and use testing approaches not reliant on vertebrate animals whenever requesting or generating new information, the revisions to TSCA provide a framework for implementation of the National Academy of Sciences report *Toxicity Testing in the 21st Century: A vision and a strategy*. A lack of standard testing requirements represents an opportunity to implement flexible, responsive tiered testing frameworks to gather information the Agency needs to evaluate chemical safety outside of the "check box." EPA has released a strategy outlining how it will work to reduce and replace animal tests within its regulatory jurisdiction. It has also begun accepting New Approach Methodologies (NAMs) in place of, for example, the Local Lymph Node Assay. For continued progress it is essential that resources are dedicated to continuing scientific development such that the Adverse Outcome Pathway framework can serve as a source of potential new methods for toxicity assessment as well as a basis for supporting the validity of NAMs, overcoming some of the challenges with traditional validation. This presentation will offer a look at how policies and guidance enacted so far relate to NAM implementation, highlight opportunities for stakeholder involvement and international cooperation, and suggest key recommendations for continued momentum in implementing 21st-century regulatory toxicology.

Audience Questions for Speaker(s) – 10 minutes

Message

From: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
Sent: 2/23/2018 8:12:10 PM
To: Brozena, Sarah [Sarah_Brozena@americanchemistry.com]
CC: Pierce, Alison (Pierce.Alison@epa.gov) [Pierce.Alison@epa.gov]; Scheifele, Hans (Scheifele.Hans@epa.gov) [Scheifele.Hans@epa.gov]
Subject: RE: GlobalChem panel conference call
Attachments: Jeff Morris Global Chem New Chemicals.pptx

Sarah,

Attached are my slides. See you next week.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M)
Washington, DC 20460

(202) 564-3810

From: Brozena, Sarah [mailto:Sarah_Brozena@americanchemistry.com]
Sent: Thursday, February 22, 2018 3:20 PM
To: Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: GlobalChem panel conference call

Thanks so much, Jeff.
Sarah

From: Morris, Jeff [mailto:Morris.Jeff@epa.gov]
Sent: Thursday, February 22, 2018 3:17 PM
To: Brozena, Sarah <Sarah_Brozena@americanchemistry.com>
Cc: Clark, Sharon <Clark.Sharon@epa.gov>
Subject: RE: GlobalChem panel conference call

Hi Sarah. Yes, sorry I missed the call, but I will be ready to go first. I aim to get my slides to you tomorrow. If that becomes a problem I will let you know before the end of the day.

Jeff

From: Brozena, Sarah [mailto:Sarah_Brozena@americanchemistry.com]
Sent: Thursday, February 22, 2018 1:41 PM

To: Morris, Jeff <Morris.Jeff@epa.gov>
Cc: Clark, Sharon <Clark.Sharon@epa.gov>
Subject: GlobalChem panel conference call

Jeff:

Sorry we missed you on our 12 noon call today about the GlobalChem Panel, "Year One: Lessons Learned and Keys to Moving Ahead" (10 a.m. to 11:15 a.m. on March 1), on which you're a panelist. I'm sure you're busy.

This was just a follow-up organizing call to make sure you all are ready (or close to ready) for the GlobalChem panel and to answer any questions you might have. On our last call Jan. 24, you said your presentation would cover 1) what's coming on the TSCA implementation front in 2018 (2 minutes on that) and the better part of your presentation would be on Section 5 – lessons learned. In January, you thought you could cover the Section 5 part of your talk in about 8 minutes. So you were figuring a 10 minute total presentation. To allow enough time for my introductions of you all and for anticipated questions from the audience, I was figuring everyone should plan about 12 minutes on their presentations. So you have a few more minutes than what you suggested in January, if you need it.

You'll be the first speaker. You'll be followed by Mark Duvall of Beveridge and Diamond whose presentation is titled: Conditions of Use under TSCA Sections 5 and 6. Mark sent everyone his near final slides earlier this morning, but he'll be making some formatting changes later today. Let me know if you have any questions about his slides.

The third speaker will be Lynn Dekleva of Dupont who will speak about the Inventory reset – and in particular some of the challenges of that reporting. I forwarded Lynn's draft slides to you and Mark this morning. Since then, Lynn has made a few corrections to the numbers on slide #2.

As I told the two of them on the call today, in order to get your presentations onto the "jump drive" that GlobalChem participants will receive with their meeting materials when they sign in, your presentation needs to be completed by tomorrow, Feb. 23. Do you expect you'll be able to meet that deadline? If not, when do you expect to get them to me (before March 1)? Let me know so that I can inform the GlobalChem meeting staff.

Let me know if you have any questions or concerns.

See you next week.

Thanks,
Sarah

Sarah H. Brozena

Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second St., NE
Washington, DC 20002
202-249-6403
Sarah_Brozena@americanchemistry.com

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www.americanchemistry.com



EPA's New Chemicals Program

Jeff Morris, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency



Overview

EPA's New Chemicals Program

- TSCA Determinations
- Current Approach
- Pre-Submission
- Path Forward



New Chemicals Background

- 2016 Amendments to TSCA
 - Required EPA to make affirmative finding on new chemicals and significant new uses of existing chemicals, before they can enter the market
 - Effective immediately
 - New chemicals determinations made using risk-based approach, considering hazard and exposure, based on conditions of use
- Conditions of use
 - Means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, use, or disposed of.



New Chemicals

Presents an unreasonable risk

- Section 5(f) order
- Section 6(a) proposed rule
- Restriction/prohibition of manufacturing, processing, distribution, or disposal

Not likely to present an unreasonable risk

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the FR

Information is insufficient to permit a reasoned evaluation of the risk.

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Insufficient Information to permit a reasoned evaluation **and may present unreasonable risk**

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required



Current Approach

- At December 2017 public meeting, EPA presented and asked for comment on EPA's current working approach to make decisions on new chemical notices
- Intended conditions of use
 - In general, these are the circumstances around manufacture, processing, distribution in commerce, use, or disposal as stated in the submission (original or amended).
 - In general, EPA will consider the amended conditions of use to be the intended conditions of use.



Current Approach

- Reasonably foreseen conditions of use
 - Identification of any reasonably foreseen conditions of use will be fact- or knowledge-specific; based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission.



Pre-Submission Support

- Two common issues with submissions
 - Information does not allow for refinement of risk assessment
 - Submitter has useful information (e.g., analog data) not provided to EPA
- New *draft* Points to Consider document
 - Will provide concise guidance to strengthen PMN submissions – largely based on existing documentation
 - Will promote more robust submissions, supported by robust pre-submission consultation effort



Path Forward

- Considering public comments from public meeting and on documents released in connection with the meeting
- Continuing to develop and revise as appropriate EPA's current approach to new chemicals
- Finalizing Points to Consider document and encouraging pre-submission consultation
 - Considering comments received
- Improving data systems to enhance ability to track, search and manage new chemical reviews
- Identifying opportunities to streamline processing
- Promoting transparency
- Continuing to improve overall performance



For More Information

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>

Contact EPA at

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/forms/assessing-and-managing-chemicals-under-tsca>

Message

From: Morris, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=55C34872E6EA40CAB78BE910AEC63321-MORRIS, JEFF]
Sent: 2/22/2018 8:16:54 PM
To: Brozena, Sarah [Sarah_Brozena@americanchemistry.com]
CC: Clark, Sharon [Clark.Sharon@epa.gov]
Subject: RE: GlobalChem panel conference call

Hi Sarah. Yes, sorry I missed the call, but I will be ready to go first. I aim to get my slides to you tomorrow. If that becomes a problem I will let you know before the end of the day.

Jeff

From: Brozena, Sarah [mailto:Sarah_Brozena@americanchemistry.com]
Sent: Thursday, February 22, 2018 1:41 PM
To: Morris, Jeff <Morris.Jeff@epa.gov>
Cc: Clark, Sharon <Clark.Sharon@epa.gov>
Subject: GlobalChem panel conference call

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Let me know if you have any questions or concerns.

See you next week.

Thanks,
Sarah

Sarah H. Brozena

Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second St., NE
Washington, DC 20002
202-249-6403
Sarah_Brozena@americanchemistry.com

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Appointment

From: Morris, Jeff [Morris.Jeff@epa.gov]
Sent: 1/12/2018 5:53:22 PM
To: Morris, Jeff [Morris.Jeff@epa.gov]; Blunck, Christopher [Blunck.Chris@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Schechter, Kathryn [Schechter.Kathryn@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Ross, Adam [ross.adam@epa.gov]; lbergeson@lawbc.com
CC: Mottley, Tanya [Mottley.Tanya@epa.gov]
Subject: Discuss Polymer Regulatory Flags w/ Lynn Bergeson
Attachments: 00211098.pdf
Location: DCRoomEast3371A/DC-EPA-EAST-OCSPP-OPPT

Start: 2/21/2018 6:00:00 PM
End: 2/21/2018 7:00:00 PM
Show Time As: Busy

**Purpose: Polymer Regulatory Flags –
Jan 21 is confirmed with Lynn Bergeson**

Meeting Location:

US Environmental Protection Agency
William Jefferson Clinton East Building
1201 Constitution Avenue, NW
Conference Room: 3371A (3rd Floor)
Washington DC 20460

Please bring photo identification and once through security, please have them call (202) 564-3810 for an escort to the meeting location.

TELECONFERENCE LINE:

CONFERENCE PHONE NUMBER:
CONFERENCE ID:

Ex. 6 Personal Privacy (PP)

POC:

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037

T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Email: lbergeson@lawbc.com

May 31, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Dr. Morris:

We took note of the recent determination by the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) under Section 5(a)(3)(C) of the Toxic Substances Control Act (TSCA) concerning a premanufacture notification (PMN) polymer that evidently was intended to be manufactured in a way that met the polymer exemption at 40 C.F.R. § 723.250. The specific PMN is:

Number: P-17-0227

TSCA Section 5(a)(3) Determination: Chemical substance not likely to present an unreasonable risk (5(a)(3)(C)).

Chemical Name:

Ex. 4 CBI

Ex. 4 CBI

Polymer exemption flag: The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 C.F.R. § 723.250(e)(1), in addition to meeting the definition of polymer at 40 C.F.R. § 723.250(b).

Ex. 5 Attorney Client (AC)

Jeffery Morris, Ph.D.
May 31, 2017
Page 2

We also want to make available to OPPT a relevant work product that relates to the issue of using the chemical name to assist in managing new polymers. The enclosed paper

Ex. 5 Attorney Client (AC)

Sincerely,



Lynn L. Bergeson

Attachment

cc: Ms. Wendy Cleland-Hamnett (w/attachment) (via e-mail)
Nancy B. Beck, Ph.D. (w/attachment) (via e-mail)
Mr. Ryan Jackson (w/attachment) (via e-mail)
Mandy Gunasekara, Esquire (w/attachment) (via e-mail)
Ms. Brittany Bolen (w/attachment) (via e-mail)
Mr. Byron Brown (w/attachment) (via e-mail)
Tanya H. Mottley, Ph.D. (w/attachment) (via e-mail)
Mr. Ryan Schmit (w/attachment) (via e-mail)

Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

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Ex. 5 Attorney Work Product (AWP)

Ex. 5 Attorney Work Product (AWP)

Appointment

From: Henry, Tala [Henry.Tala@epa.gov]
Sent: 3/14/2019 12:38:12 PM
To: Henry, Tala [Henry.Tala@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Franz, Christina [Christina_Franz@americanchemistry.com]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Sahar_Osman-Sypher@americanchemistry.com; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Mark Duvall [MDuvall@bdlaw.com]; Lisa Marie Nespoli [lisamarie.nespoli@covestro.com]; Mark Joseph McKinney [mark.mckinney@basf.com]; Marcia Levinson [marcia.levinson@covestro.com]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Adam Kuhl [adam_kuhl@huntsman.com]; Wormell, Lance [Wormell.Lance@epa.gov]; Arnold, Scott (M) [SMArnold@dow.com]; Cynthia Graham [cynthia_graham@huntsman.com]
Subject: Meeting with ACC
Attachments: ACC letter to EPA re April 10 meeting on isocyanates - 4-5-19.pdf; ACC_EPA Meeting Agenda on Isocyanates-Based SNURs 2019 04 10.pdf
Location: DCRoomEast3371A/DC-EPA-EAST-OCSPP-OPPT
Start: 4/10/2019 12:00:00 PM
End: 4/10/2019 1:00:00 PM
Show Time As: Busy

Teleconference Line:

Ex. 6 Personal Privacy (PP)

Conference ID: Ex. 6 Personal Privacy (PP)

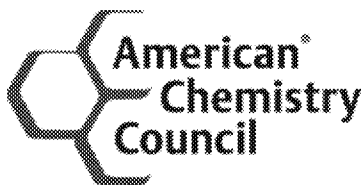
LEADER: Tala

Meeting Location:

Environmental Protection Agency
William Jefferson Clinton East Building
1201 Constitution Avenue NW
Conference Room: 3371A (3rd Floor)
Washington, DC 20460

Please bring photo identification and once through security, please have them call (202) 564-3810 for an escort to meeting location.

Please provide list of names of five or more attendees coming from your group – this will speed up clearing security check-in.



April 5, 2019

By email to henry.tala@epa.gov

Dr. Tala Henry (74013T)
Acting Deputy Director for Programs
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: EPA's Approach to Isocyanate-Based Polymers Under TSCA Section 5

Dear Dr. Henry:

On behalf of the American Chemistry Council and its Diisocyanates and Aliphatic Diisocyanates Panels (collectively ACC), thank you for scheduling a meeting with us on April 10 at 8:00 a.m. This letter presents the questions ACC would like to discuss at the meeting.

The purpose of the meeting is to help ACC better understand EPA's approach to isocyanate-based polymers under section 5 of TSCA. The outcome of the meeting could help ACC and its members, and the customers of those members, develop polymers with improved risk profiles, and also help expedite the SNUR rulemaking process.

As a preliminary matter, we point out that EPA published an Action Plan for methylene diphenyl diisocyanate (MDI) and related compounds in April 2011. Since then, it has issued final or proposed SNURs for at least 58 isocyanate-based polymers and prepolymers. Of those 58 SNURs, EPA has finalized 28. A total of 30 SNURs, more than half, remain under review. EPA last finalized a SNUR for an isocyanate-based polymer in December 2014, over four years ago. See Attachment 1 for details.

ACC has submitted comments on almost all of the 30 proposed SNURs raising concerns that – to date – EPA has not answered. We hope that the meeting will address those concerns.

1. When will EPA update the Chemical Categories description for diisocyanates?

ACC would like to know when EPA will update at least the Chemical Categories description on diisocyanates. EPA has told ACC that it no longer follows the guidance in that description. ACC members and their customers rely on EPA guidance as to what limits are acceptable, so an updated description is critical to ensuring our members have clear guidance regarding the parameters EPA considers when issuing these SNURs.

2. Why does EPA propose maximum percentages for residual isocyanates in some section 5(e) orders and SNURs for isocyanate-based polymers, and not in others, and use differing percentages when it does propose these limitations?

In several recent SNURs for isocyanate-based polymers, EPA has proposed a ceiling on residual isocyanate content. ACC would also like to understand what EPA means by “residual isocyanate.” Does this refer only to unreacted monomer? It is important for EPA to clarify this term, because EPA does not have authority under section 5 to regulate the monomer itself as it is used as a reactant (an existing use), and the monomer is not part of the polymer or pre-polymer that is the PMN substance.

The proposed SNURs with a ceiling include those in the following PMN substances:

- P-18-51: “It is a significant new use to import the substance with greater than 0.1% isocyanate content.”
- P-17-374: “It is a significant new use to import the substance with more than 0.1% residual isocyanate.”
- P-17-361: “It is a significant new use to manufacture the substance containing greater than 0.25% residual isocyanate”
- P-17-304: “It is a significant new use to manufacture (includes importing) the substance to contain more than 0.1% residual isocyanate by weight.”
- P-17-222: “It is a significant new use to import the chemical substance containing greater than 0.15 percent residual isocyanate.”
- P-17-170: “It is a significant new use to manufacture the chemical substance containing greater than 0.1 percent residual isocyanate”
- P-17-10: “It is a significant new use to manufacture the chemical substance ... containing greater than 0.1% residual isocyanate.”
- P-16-493: “It is a significant new use to import the PMN substance to contain more than 0.1% residual isocyanate by weight.”
- P-16-363: “It is a significant new use to manufacture, process, or use the substance with a residual of free isocyanate monomers greater than 0.1 percent by weight.”
- P-16-99: “It is a significant new use to manufacture the chemical substance containing greater than 0.2% residual isocyanate.”
- P-15-707: “A significant new use is any manufacture, processing, or use of the PMN substance with more than [0.1]% residual isocyanate by weight.”¹

¹ The proposed regulatory text refers to “1%”, but the preamble refers to “0.1%”. ACC assumes that EPA meant to refer to “0.1%” in the regulatory text.

- P-15-706: “A significant new use is any manufacture, processing, or use of the PMN substance with more than 0.1% residual isocyanate by weight.”

Thus, EPA has proposed a maximum percentage limitation in 12 of the 58 SNURs for isocyanate-based polymers since April 2011. It proposed a 0.1% limit (variously phrased) for 10 of them. The other percentages were 0.15%, 0.2%, and 0.25%.

ACC would like to understand why EPA proposed a maximum percentage limitation in some section 5(e) orders and SNURs for isocyanate-based polymers and not in others, and why it selected 0.1% in most cases, but proposed higher percentages in three instances.

3. Why does EPA propose limits on average molecular weight in some section 5(e) orders and SNURs for isocyanate-based polymers, and not in others, and use differing molecular weight limits when it does propose them?

In several recent SNURs for isocyanate-based polymers, EPA has proposed a ceiling on low-molecular weight species. They include proposed SNURs for the following PMN substances:

- P-18-40: “It is a significant new use to import the substance if the number average molecular weight is less than or equal to 1000 daltons.”
- P-17-374: “It is a significant new use to import the substance at a number average molecular weight less than 1000 daltons.”
- P-17-361: “It is a significant new use to manufacture the substance ... [with] an average molecular weight less than 2,280 daltons.”
- P-17-170: “It is a significant new use to manufacture the chemical substance ... [with] an average molecular weight below 1,000 daltons.”
- P-17-10: “It is a significant new use to manufacture the chemical substance with an average molecular weight below 2,000 daltons”
- P-15-559: “A significant new use of the substance is manufacture of the substance where the average molecular weight is below 7,500 daltons, and where any molecular weight species is below 1,000 daltons.”
- P-15-278: “The significant new use is manufacture of the substance where the average molecular weight is below 2,500 daltons and where any molecular weight species is below 1,000 daltons.”
- P-12-326: “The significant new uses are: (i) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(j) (manufacture, processing, or use where the molecular weight is 1000 daltons or more).”² [Note: presumably should be 1000 daltons or less.]

Thus, EPA proposed a minimum molecular weight in 8 of the 58 SNURs since April 2011. The minimums proposed have included 1,000 daltons, 2,000 daltons, 2,500 daltons, and 2,280 daltons. In addition, EPA has expressed concerns about average molecular weights below 7,500 daltons.

² The text should probably refer to “1000 daltons or less,” not “1000 daltons or more.” The preamble refers to “1000 daltons or less.”

Some of these proposed minimums and the statement of concern are inconsistent with the 2010 Chemical Categories section on diisocyanates. It states:

Structures with an isocyanate equivalent weight of $\geq 5,000$ are presumed not to pose a hazard under any condition. Typically, concerns are confined to those species with molecular weights $< 1,000$.

ACC would like to understand why EPA proposed a minimum average molecular weight in some section 5(e) orders and SNURs for isocyanate-based polymers and not others, and why it selected 1,000 daltons in most cases, but proposed higher molecular weights in three cases.

4. How Did EPA Calculate the NCEL of 0.9 mg/m³?

For 3 of the 58 SNURs for isocyanate-based polymers since April 2011, EPA has proposed a New Chemical Exposure Limit (NCEL) of 0.9 mg/m³. They are the proposed SNURs for P-16-99, P-15-707, and P-15-706.

The SNUR for P-04-834 set a NCEL of 0.05 mg/m³ TWA₈. In addition, the section 5(e) order for P-16-493 cautioned:

Inhalation exposure should be limited to < 0.05 mg/m³ as an 8-hours time-weighted average (TWA) for combined polyisocyanates and diisocyanates.

ACC would like to understand the basis for these NCELs and how EPA calculated the 0.9 mg/m³ NCEL and the 0.05 mg/m³ NCEL.

5. Which health effects does EPA associate with isocyanates?

As indicated in the attached table, EPA has described its expected health effects from isocyanate-based polymers in widely varying terms. It mentioned dermal and respiratory sensitization consistently. In some section 5(e) orders and SNURs, however, EPA has asserted concerns for oncogenicity, mutagenicity, neurotoxicity, developmental toxicity, and lung toxicity based on cationic binding. Most, however, have not referred to those health effects.

ACC would like to understand which health effects of isocyanates are of concern to EPA; why it cites some health effects for some substances and not others; and whether the isocyanate-based concerns vary from substance to substance and, if so, what the basis is for EPA's selection of particular health effects for a given SNUR.

6. Has EPA reviewed the basis for its assertion that isocyanates are the leading cause of occupational asthma, with an incidence rate as high as 20%?

The section 5(f) order for P-17-24 and P-17-25 declared:

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (see Refs. 1 and 2).

This statement is taken verbatim from the proposed SNUR for toluene diisocyanates and related compounds, 80 Fed. Reg. 2068, 2070 (Jan. 15, 2015). Numerous section 5(e) orders do not make this statement explicitly, but instead they refer to the 2006 NIOSH Alert, “Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications,” which states:

Isocyanates are the leading attributable chemical cause of occupational asthma in the United States and many other industrialized countries [Tarlo et al. 1997b].

ACC has reviewed the sources cited by EPA and NIOSH for this assertion and found them to be outdated and inaccurate. See Attachment 2.

ACC encourages EPA to review the more recent scientific literature, which does not support the assertion that diisocyanates are the leading cause of occupational asthma. Recent data show a consistent picture of a decline in asthma rates associated with diisocyanates over the last decade, even as production rates of diisocyanates have increased. The reduction in diisocyanate-related occupational asthma is primarily due to a variety of product stewardship activities, including education and training, enhanced worker awareness, improved work practices, use of less volatile diisocyanate forms (e.g., pre-polymers), improved engineering controls (e.g., containment and/or ventilation), better medical surveillance programs, minimization of peak exposures, and continuing emphasis on compliance with existing exposure standards. These product stewardship efforts are key to further reductions in cases.

According to the NIOSH Work-Related Lung Disease Surveillance System (eWoRLD), in the four U.S. states surveyed (California, Massachusetts, Michigan, and New York) the most recent work-related asthma statistics from 2009-2012 indicate that diisocyanates are not in the top ten “frequently reported agent categories associated with work-related asthma,” falling to number 19 (1.0% of work-related asthma cases).

7. Why is EPA not finalizing SNURs for isocyanate-based polymers?

EPA currently has 30 proposed SNURs for isocyanate-based polymers pending review. It has not finalized a proposed SNUR or a direct final SNUR for an isocyanate-based polymer since December 2014, over four years ago.

Any manufacturers and processors of these polymers, other than the PMN submitters, should be subject to the same restrictions as those to which the PMN submitters are subject.

ACC would like to understand why EPA continues to issue direct final SNURs and/or proposed SNURs for isocyanate-based polymers, but does not finalize them. ACC also requests a response to the comments it has submitted on many of the pending SNURs.

8. What is the significance of the medical surveillance requirement in a recent section 5(e) order and proposed SNUR?

For the first time that ACC is aware, EPA has included a medical surveillance requirement in a section 5(e) order and proposed SNUR. The proposed SNUR for P-17-231 states:

It is a significant new use to manufacture the substance without conducting medical surveillance as specified in the Order.

It is not clear whether the medical surveillance requirement was prompted by EPA concerns for isocyanates or for other moieties in that polymer.

ACC would like to understand why EPA included a medical surveillance requirement in that section 5(e) order and proposed SNUR (and, in particular, whether it was prompted by a concern about isocyanates). ACC would also like to know whether EPA intends to require medical surveillance in future section 5(e) orders and SNURs for isocyanate-based polymers, and, if so, what the basis is for this requirement and the intended scope of that medical surveillance.

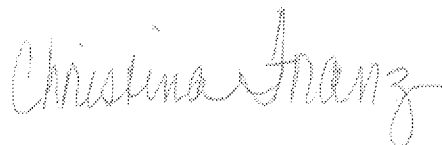
Moving forward, ACC would very much like to partner with EPA to resolve the issues outlined above. ACC is available to educate Agency staff on our chemistries to help expedite chemical reviews and address EPA's concerns. In addition, we would like to work with EPA scientists to design test plans to develop toxicological data to fulfill apparent data gaps, particularly for isocyanate prepolymers.

We look forward to the opportunity to discuss these suggestions with your staff at the April 10 meeting. In the meantime, if you have questions or comments, please contact Christina Franz at (202) 249-6406 and christina_franz@americanchemistry.com, or Sahar Osman-Sypher at (202) 249-6721 and sahar_osman-sypher@americanchemistry.com.

Sincerely,



Sahar Osman-Sypher
Director, Diisocyanates and Aliphatic
Diisocyanates Panels



Christina Franz
Senior Director, Regulatory & Technical
Affairs

Attachments

cc: Alexandra Dunn
Dr. Jeffery Morris

Attachment 1

SNURs for Isocyanate-Based Polymers Since April 2011

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-18-51	Proposed 40 C.F.R. § 721.11242 84 Fed. Reg. 9999 (Mar. 19, 2019) (proposed SNUR)	Comment period closes May 3, 2019.	§ 5(e) order: None specifically identified as attributable to isocyanates.	No	“It is a significant new use to import the substance with greater than 0.1% isocyanate content.”
P-18-40	Proposed 40 C.F.R. § 721.11239 84 Fed. Reg. 9999 (Mar. 19, 2019) (proposed SNUR)	Comment period closes May 3, 2019.	§ 5(e) order: None specifically identified as attributable to isocyanates.	No	“It is a significant new use to import the substance if the number average molecular weight is less than or equal to 1000 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-374	Proposed 40 C.F.R. § 721.11239 84 Fed. Reg. 9999 (Mar. 19, 2019) (proposed SNUR)	Comment period closes May 3, 2019.	§ 5(e) order unavailable. None specifically identified in SNUR preamble as attributable to isocyanates.	No	“It is a significant new use to import the substance with more than 0.1% residual isocyanate. It is a significant new use to import the substance at a number average molecular weight less than 1000 daltons.”
P-17-361	Proposed 40 C.F.R. § 721.11211 83 Fed. Reg. 57634 (Nov. 15, 2018) (proposed SNUR)	Under EPA review. Comment period closed Dec. 31, 2018.	§ 5(e) order: “The concern for eye and skin irritation, and sensitization (dermal and respiratory) is based primarily on the isocyanate moiety.”	No	“It is a significant new use to manufacture the substance containing greater than 0.25% residual isocyanate or an average molecular weight less than 2,280 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-304	Proposed 40 C.F.R. § 721.11206 83 Fed. Reg. 57634 (Nov. 15, 2018) (proposed SNUR)	Under EPA review. Comment period closed Dec. 12, 2018.	§ 5(e) order: “Toxicological Endpoints of Concern: There is concern for sensitization EPA's estimate of the human health hazard of the PMN substance is based on its estimated physical/chemical properties and other structural information, including the presence of Low Molecular Weight (LMW) moieties in the polymer.”	No	“It is a significant new use to manufacture (includes importing) the substance to contain more than 0.1% residual isocyanate by weight.”
P-17-231	Proposed 40 C.F.R. § 721.11112 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 43607 (Aug. 27, 2019) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “No significant health concerns for the PMN substance as it is now. If made differently (different ratio of monomers), there may be isocyanate moieties present that would be of concern for human health endpoints of dermal sensitization, respiratory sensitization, lung effects, neurotoxicity and developmental toxicity. Basis: Diisocyanate Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications As the PMN substance is currently described, there is no risk to workers, but if the substance is made with a different percent residual of isocyanate, there may be unreasonable risk to workers.”	No	“It is a significant new use to manufacture the substance without conducting medical surveillance as specified in the Order.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-222	Proposed 40 C.F.R. § 721.11111 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 43607 (Aug. 27, 2019) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “There are concerns for dermal sensitization, respiratory sensitization, lung effects, neurotoxicity and developmental toxicity. Basis: Diisocyanate Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications As manufactured, there are no risks to workers for exposure of the PMN. Due to the possibility of isocyanate residuals if it is made different, there is concern for sensitization. Exposure to diisocyanate may cause the following effects: skin irritation and allergic reaction, respiratory irritation, respiratory sensitization, and lung toxicity; some diisocyanates also may cause cancer. It is especially important to note that contact with the skin may lead to respiratory sensitization or cause other allergic reactions. Workers should take precaution to avoid breathing vapors, mists or aerosols. Inhalation exposure should be limited to <0.05 mg/m ³ as an 8-hours time-weighted average (TWA) for combined polyisocyanates and diisocyanates.”	No	“It is a significant new use to import the chemical substance containing greater than 0.15 percent residual isocyanate.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-170	Proposed 40 C.F.R. § 721.11107 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 43607 (Aug. 27, 2019) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “Further, if the polymer were made differently there could be other hazards. For example, if made differently, there could be free isocyanates. See [Diisocyanate Chemicals Category ...]	No	“It is a significant new use to manufacture the chemical substance containing greater than 0.1 percent residual isocyanate or an average molecular weight below 1,000 daltons.”

P-17-24	<p>Proposed 40 C.F.R § 721.11159</p> <p>83 Fed. Reg. 49806 (Oct. 3, 2018) (direct final SNUR); 83 Fed. Reg. 49903 (Oct. 3, 2019) (proposed SNUR)</p>	<p>Direct final SNUR withdrawn Dec. 4, 2018. Proposed SNUR under review.</p>	<p>§ 5(f) order: “Respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety Diisocyanates are well-known dermal, eye, and inhalation irritants and sensitizers based on worker data. They have been documented in the workplace to cause asthma and respiratory problems, such as hypersensitivity pneumonitis, an inflammation of the lungs. In severe cases, there have been reported fatal reactions Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (see Refs. 1 and 2). Once a worker is sensitized to diisocyanates, subsequent exposures can trigger severe asthma attacks. Spray application and heated processes are associated with higher incidences of asthma than other application methods because they can generate airborne isocyanate vapors and mists, which lead to worker exposure via the respiratory and dermal routes. Most workers who develop diisocyanate asthma have experienced long periods of exposure (months or longer); however, the minimum exposure to isocyanates that can elicit sensitization responses or asthma is unknown. In addition, immune response and subsequent disease in humans can vary significantly</p>	No	No
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PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
			between individuals (Ref. 3). Fatalities linked to diisocyanate exposures in sensitized persons have been reported (Refs. 4 and 5.) More information on isocyanate effects, could be found in the Diisocyanate Chemicals Category ...; or in the publication from Department of Health and Human Services, Center for Disease Control 'NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications'”		
P-17-25	Proposed 40 C.F.R. § 721.11160 83 Fed. Reg. 49806 (Oct. 3, 2018) (direct final SNUR); 83 Fed. Reg. 49903 (Oct. 3, 2019) (proposed SNUR)	Direct final SNUR withdrawn Dec. 14, 2018. Proposed SNUR under review.	Same as above	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-10	Proposed 40 C.F.R. § 721.11084 83 Fed. Reg. 40986 (Aug. 17, 2018) (direct final SNUR); 83 Fed. Reg. 41039 (Aug. 17, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 11, 2018. Proposed SNUR under review.	§ 5(e) order: None specifically identified as attributable to isocyanates.	No	“It is a significant new use to manufacture the chemical substance with an average molecular weight below 2,000 daltons or containing greater than 0.1% residual isocyanate.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-16-493	Proposed 40 C.F.R. § 721.11125 83 Fed Reg. 47004 (Sept. 17, 2018) (direct final SNUR); 83 Fed. Reg. 47026 (Sept. 17, 2018) (proposed SNUR)	Direct final SNUR withdrawn Nov. 16, 2018. Proposed SNUR under review.	§ 5(e) order: “Basis: Diisocyanates Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Lining and Related Applications Due to the possibility of isocyanate residuals there is concern for sensitization. Exposure to diisocyanate may cause the following effects: skin irritation and allergic reaction, respiratory irritation, respiratory sensitization, and lung toxicity; some diisocyanates also may cause cancer. It is especially important to note that contact with the skin may lead to respiratory sensitization or cause other allergic reactions.”	No, but the section 5(e) order cautioned, “Inhalation exposure should be limited to < 0.05 mg/m ³ as an 8-hours time-weighted average (TWA) for combined polyisocyanates and diisocyanates.”	“It is a significant new use to import the PMN substance to contain more than 0.1% residual isocyanate by weight.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-16-363	Proposed 40 C.F.R. § 721.11101 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 63607 (Aug. 27, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “Toxicological Endpoints of Concern: irritation to all moist tissues and sensitization. Basis: Diisocyanate Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications.... Also, there are concerns for lung toxicity based on cationic binding to the lung tissue.”	No	“It is a significant new use to manufacture, process, or use the substance with a residual of free isocyanate monomers greater than 0.1 percent by weight.”
P-16-99	Proposed 40 C.F.R. § 721.11098 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 63607 (Aug. 27, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: None specifically identified as attributable to isocyanates.	NCEL = 0.9 mg/m ³ TWA ₈	“It is a significant new use to manufacture the chemical substance containing greater than 0.2% residual isocyanate.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-707	Proposed 40 C.F.R. § 721.11030 83 Fed. Reg. 37702 (Aug. 1, 2018) (direct final SNUR); 83 Fed. Reg. 37455 (Aug. 1, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 11, 2018. Proposed SNUR under review.	None in the § 5(e) order. The SNUR preamble states: “There are also concerns ... for sensitization if there are residual isocyanates.”	NCEL = 0.9 mg/m ³ TWA ₈	“A significant new use is any manufacture, processing, or use of the PMN substance with more than 1% residual isocyanate by weight.” [Note: “1%” may be an error; the preamble refers to “manufacture of the PMN substance to contain no more than 0.1% isocyanate by weight.”]
P-15-706	Proposed 40 C.F.R. § 721.11029 83 Fed. Reg. 37702 (Aug. 1, 2018) (direct final SNUR); 83 Fed. Reg. 37455 (Aug. 1, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 11, 2018. Proposed SNUR under review.	§ 5(e) order: None specifically identified as attributable to isocyanates. The SNUR preamble states: “There are also concerns ... for sensitization if there are residual isocyanates.”	NCEL = 0.9 mg/m ³ TWA ₈	“A significant new use is any manufacture, processing, or use of the PMN substance with more than 0.1% residual isocyanate by weight.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-559	Proposed 40 C.F.R. § 721.10920 81 Fed. Reg. 30452 (May 16, 2016) (direct final SNUR); 81 Fed. Reg. 74755 (Oct. 27, 2016) (proposed SNUR)	Direct final SNUR withdrawn July 14, 2016. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PMN substance where the average molecular weight is below 7,500 daltons and any molecular weight species is below 1,000 daltons EPA has determined, however, that any manufacture of the PMN substance with an average molecular weight below 7,500 daltons, and where any molecular weight species is below 1,000 daltons may cause serious health effects. For new isocyanates submitted as PMNs, EPA expects to issue TSCA section 5(e) orders imposing 0.1% limits on total residual isocyanates and greater levels of respiratory protection (at least an APF of 50, or 1000 if used in a process that generates a vapor or particulate), and no consumer use. The Agency would then likely issue a SNUR defining the significant new use as total residual isocyanates exceeding that 0.1% limit and any use in a consumer product.”	No	“A significant new use of the substance is manufacture of the substance where the average molecular weight is below 7,500 daltons, and where any molecular weight species is below 1,000 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-378	Proposed 40 C.F.R. § 721.10913 Direct final SNUR, 81 Fed. Reg. 30452 (May 16, 2016); proposed SNUR, 81 Fed. Reg. 74755 (Oct. 27, 2016)	Direct final SNUR withdrawn July 14, 2016. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No
P-15-278	Proposed 40 C.F.R. § 721.10874 80 Fed. Reg. 59583 (Oct. 2, 2015) (direct final SNUR); 81 Fed. Reg. 21830 (Apr. 13, 2016) (proposed SNUR)	Direct final SNUR withdrawn Nov. 20, 2015. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PMN substance when the average molecular weight is below 2500 daltons and any molecular weight species is below 1000 daltons.”	No	“The significant new use is manufacture of the substance where the average molecular weight is below 2,500 daltons and where any molecular weight species is below 1,000 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-247	Proposed 40 C.F.R. § 721.10873 80 Fed. Reg. 59583 (Oct. 2, 2015) (direct final SNUR); 81 Fed. Reg. 21830 (Apr. 13, 2016) (proposed SNUR)	Direct final SNUR withdrawn Nov. 11, 2015. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety.”	No	No
P-15-221	Proposed 40 C.F.R. § 721.10871 80 Fed. Reg. 59583 (Oct. 2, 2015) (direct final SNUR); 81 Fed. Reg. 21830 (Apr. 13, 2016) (proposed SNUR)	Direct final SNUR withdrawn Nov. 20, 2015. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation and sensitization to the skin and lungs.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-14-357	Direct final SNUR, 40 C.F.R. § 721.10788 79 Fed. Reg. 63821 (Oct. 27, 2014)	Effective Dec. 26, 2014.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization.”	No	No
P-14-60	Proposed 40 C.F.R. § 721.10762 79 Fed. Reg. 38464 (July 8, 2014) (direct final SNUR); 80 Fed. Reg. 858 (Jan. 9, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization to persons exposed to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-619	Proposed 40 C.F.R. § 721.10744 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No
P-13-618	Proposed 40 C.F.R. § 721.10743 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-617	Proposed 40 C.F.R. § 721.10742 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No
P-13-563	Proposed 40 C.F.R. § 721.10741 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of analogous diisocyanates, EPA identified concerns for oncogenicity, mutagenicity, respiratory and dermal sensitization and lung and mucous membrane irritation from exposure to the PMN substance via inhalation and dermal exposures.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-559	40 C.F.R. § 721.10795 80 Fed. Reg. 5457 (Feb. 2, 2015) (direct final SNUR)	Effective Apr. 3, 2015.	No § 5(e) order – this is a non-order SNUR. None specifically identified in SNUR preamble as attributable to isocyanates.	No	No
P-13-471	Proposed 40 C.F.R. § 721.10723 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Apr. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for oncogenicity, mutagenicity, respiratory and dermal sensitization, and lung and mucous membrane irritation to workers exposed to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-393	Proposed 40 C.F.R. § 721.10720 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Apr. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, the Agency identified concerns for dermal and respiratory sensitization, irritation to all moist tissues, and lung effects if inhaled based on the low molecular weight isocyanates.”	No	No
P-13-392	Proposed 40 C.F.R. § 721.10719 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Jan. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “EPA identified concerns for dermal and respiratory sensitization, irritation to all moist tissues, and lung effects if inhaled based on the low molecular weight isocyanates, to workers exposed to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-365	Proposed 40 C.F.R. § 721.10717 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Apr. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, and lung and mucous membrane irritation effects.”	No	No
P-13-357	40 CF.R. § 721.10788 78 Fed. Reg. 63821 (Oct. 27, 2014)	Effective Dec. 26, 2014	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation to the eye, skin, and mucous membranes; and dermal and respiratory sensitization.”	No	No
P-13-338	40 CF.R. § 721.10693 78 Fed. Reg. 48059 (Aug. 7, 2013)	Effective Oct. 7, 2013.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, irritation, and lung effects.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-232	40 C.F.R. § 721.10690 78 Fed. Reg. 48059 (Aug. 7, 2013) (direct final SNUR)	Effective Oct. 7, 2013.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanates, EPA identified concerns for sensitization as well as lung and mucous membrane irritation.”	No	No
P-13-176	40 C.F.R. § 721.10773 79 Fed. Reg. 63821 (Oct. 27 2014) (direct final SNUR)	Effective Dec. 26, 2014	No § 5(e) order – this is a non-order SNUR. None specifically identified in SNUR preamble as attributable to isocyanates.	No	No
P-13-175	40 C.F.R. § 721.10772 79 Fed. Reg. 63821 (Oct. 27, 2014) (direct final SNUR)	Effective Dec. 26, 2014	No § 5(e) order – this is a non-order SNUR. None specifically identified in SNUR preamble as attributable to isocyanates.	No	No
P-12-373	40 C.F.R. § 721.10626 77 Fed. Reg. 66149 (Nov. 2, 2012) (direct final SNUR)	Effective Jan. 2, 2013	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous acrylates and isocyanates, EPA identified concerns for respiratory and dermal sensitization and irritation to workers from exposure to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-12-326	40 C.F.R. § 721.10624 77 Fed. Reg. 66149 (Nov. 2, 2012) (direct final SNUR)	Effective Jan. 2, 2013	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanate substances, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure to the PMN substance. Specifically, the Agency expects potential toxicity to workers from dermal or inhalation exposure to the PMN substance when the molecular weight is less than 1000 daltons.”	No	“The significant new uses are: (i) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(j) (manufacture, processing, or use where the molecular weight is 1000 daltons or more).” [Note: presumably should be 1000 daltons or less.]
P-12-274	40 C.F.R. § 721.10660 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concern for sensitization from dermal and inhalation exposure to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-12-143	40 C.F.R. § 721.10659 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and respiratory exposures to the PMN substance.”	No	No
P-12-133	40 C.F.R. § 721.10658 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “based on the isocyanate moiety, the Agency identified concerns for sensitization.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-12-73	40 C.F.R. § 721.10657 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for sensitization.”	No	No
P-11-862	40 C.F.R. § 721.10298 77 Fed. Reg. 20296 (Apr. 4, 2012) (direct final SNUR)	Effective June 4, 2012	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for mutagenicity, irritation to lungs and mucous membranes, and dermal and respiratory sensitization to workers from dermal and inhalation exposure to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-314	40 C.F.R. § 721.10656 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No
P-11-313	40 C.F.R. § 721.10655 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-312	40 C.F.R. § 721.10654 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No
P-11-311	40 C.F.R. § 721.10653 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-309	40 C.F.R. § 721.10652 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No
P-11-115	40 C.F.R. § 721.10649 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-60	40 C.F.R. § 721.10661 78 Fed. Reg. 27048 (May 9, 2013) (direct final SNUR)	Effective July. 8, 2013.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on structural activity relationship (SAR) analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization and for pulmonary toxicity to workers exposed to free isocyanates.”	No	No
P-08-611	40 C.F.R. § 721.10571 77 Fed. Reg. 61118 (Oct. 5, 2012) (direct final SNUR)	Effective Dec. 4, 2012.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization and for pulmonary toxicity to workers exposed to free isocyanates.”	No	Significant new use is manufacture other than as described in the PMN, “(manufacture with all isocyanate groups reacted within the polymer).”
P-04-834	40 C.F.R. § 721.10490 77 Fed. Reg. 58666 (Sept. 21, 2012) (direct final rule)	Effective Nov. 20, 2012	§ 5(e) order unavailable. Direct final SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, pulmonary toxicity, and carcinogenicity from dermal and inhalation exposures.”	NCEL = 0.05 mg/m ³ TWA ₈	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-04-640	40 C.F.R. § 721.10643 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	§ 5(e) order unavailable. Proposed SNUR preamble: “Based on SAR analysis of test data on structurally similar diisocyanates, EPA identified concerns for dermal sensitization, respiratory sensitization, and pulmonary toxicity from exposure to the PMN substance by the inhalation and dermal routes.”	No	No
P-04-563	40 C.F.R. § 721.10343 77 Fed. Reg. 25236 (Apr. 27, 2012)	Effective June 26, 2012	No § 5(e) order – this is a non-order SNUR. SNUR preamble: None specifically identified as attributable to isocyanates.	No	No
P-03-767	40 C.F.R. § 721.10331	Effective June 26, 2012	No § 5(e) order – this is a non-order SNUR. SNUR preamble: None specifically identified as attributable to isocyanates.	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-03-762 and P-03-763	40 C.F.R. § 721.10642 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA has identified concerns for sensitization and irritation from dermal and inhalation exposure to the PMN substances.”	No	No

Attachment 2

Isocyanates Are Not a Leading Cause of Occupational Asthma

April 5, 2019

Isocyanates Are Not a Leading Cause of Occupational Asthma

EPA has asserted multiple times that:

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20%

This statement was not accurate when originally made, and it has become increasingly inaccurate with time. This paper first summarizes EPA's extensive reliance on the statement quoted above. Next, it reviews the sources on which the quoted statement relies and shows that those sources do not support the statement. It ends with a review of recent evidence that isocyanates are not now a significant cause of occupational asthma and have a low incidence rate.

In light of this evidence, EPA should stop referring to isocyanates as the leading attributable cause of occupational asthma. It should also stop referring to outdated and misleading incidence rates of isocyanate-related asthma.

1. EPA Has Repeatedly Referred to Isocyanates as the Leading Cause of Occupational Asthma, With Incidence of Up to 20%

In April 2011, EPA posted a Methylene Diphenyl Diisocyanate (MDI) And Related Compounds Action Plan and a Toluene Diisocyanate (TDI) And Related Compounds Action Plan. Both action plans asserted (p. 4):

It is well documented that isocyanate exposure is the leading cause of work-related asthma, and prevalence in the exposed workforce is estimated at 1-20% (Ott et al., 2003;¹ Bello et al., 2004).²

EPA repeated that statement in its proposed SNUR for TDI, 80 Fed. Reg. 2068, 2070 (Jan. 15, 2015):

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1–20 percent (Refs. 11 and 12).³

¹ The citation for the Ott et al. paper is Ott MG, Diller, WF, Jolly AT. 2003. Respiratory Effects of Toluene Diisocyanates in the Workplace; a Discussion of Exposure-Response Relationships. *Critical Review Toxicology* 33:1-59.

² The citation for the Bello et al. paper is Bello D, Woskie SR, Streicher RP, Liu Y, Stowe MH, Eisen EA, Ellenbecker MJ, Sparer J, Youngs F, Cullen MR, Redlich CA. 2004. Polyisocyanates in Occupational Environments: a Critical Review of Exposure Limits and Metrics. *American Journal Industrial Medicine* 46:480-491.

³ Reference 11 and 12 are to the Ott et al. and Bello et al. papers cited above.

The statement appeared again in EPA's 2017 section 5(f) order for two new isocyanate-based polymers, P-17-24 and P-17-25. It stated (p. vii):

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (see Refs. 1 and 2).⁴

In addition, EPA has issued several section 5(e) orders⁵ for other new isocyanate-based polymers that refer to the 2006 NIOSH Alert, "Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications," which states (p. 4):

Isocyanates are the leading attributable chemical cause of occupational asthma in the United States and many other industrialized countries [Tarlo et al. 1997b].

With these statements reasserted so many times, it is likely that EPA relies on them for the restrictions it imposes on new isocyanate-based polymers it reviews under section 5 of TSCA. As demonstrated in section 2 below, the statements were not accurate at the time they were originally made. As demonstrated in section 3 below, the statements are even less accurate now.

2. The Cited References Do Not Support the EPA Statements

The sources on which EPA relied for the statements noted in section 1 are more than 10 years old. They relied in turn on older papers, which cited even older papers. The Ott et al., Bello et al., and Tarlo et al. papers do not support the statements repeated by EPA.

a. Ott et al. (2003)

The 2003 Ott et al. paper, now 16 years old, was a literature review, not a primary source. It presented a very different perspective than that cited by EPA:

In the early years of the industry, annual incidence rates of occupational asthma (OA) due to TDI ranged from 1% to as high as 6%, depending on the extent of engineering and work practice controls in the various workplaces. **Since the mid-1970s, annual OA incidence rates have been < 1%**, where 8 h TDI concentrations have been maintained below 5 ppb as determined by personal monitoring, even where short-term TDI concentrations above 20 ppb and less frequently above 40 ppb were routinely detected. [Emphasis added.]

The paper did say that "diisocyanates are among the most prevalent reported causes of OA." It did not mention a 20% incidence rate, however.

b. Bello et al. (2004)

⁴ References 1 and 2 are to the Ott et al. and Bello et al. papers cited above.

⁵ Including the section 5(e) orders for PMNs P-17-231, P-17-222, P-17-24 and -25, 16-493, and 16-393.

This paper did use a 20% incidence figure for sensitization and asthma together (i.e., not specifically for asthma), citing other older studies of which none suggested an incidence rate of 20%:

However, sensitization and asthma are the primary health concerns, and **their estimated prevalence in the exposed workforce is 1-20%** [Vandenplas et al., 1993a; Bernstein, 1996; Petsonk et al., 2000; Wisnewski and Redlich, 2001; Diller, 2002]. [Emphasis added.]

The cited papers do not support the Bello et al. statement of an incidence rate of up to 20%.

The 1993 Vandenplas et al. paper,⁶ itself a literature review and now 26 years old, did not support a 20% incidence figure. It stated:

According to the results of studies with objective diagnostic tests, a **prevalence of about 10%** seems to be a reasonable approximation. [Citations omitted, emphasis added.]

It did state that “isocyanates are the principal cause of occupational asthma,” citing a 1984 paper by Davies (now 35 years old). The Davies paper did not summarize surveillance data; it included only the author’s opinion.

The 1996 Bernstein et al. paper⁷ was also a literature review and is now 23 years old. It did not suggest a ranking of the leading causes of occupational asthma. The paper suggested a prevalence of 5 to 10%:

Surveillance programs established around the world have determined that diisocyanate chemicals are the most common cause of occupational asthma. In the United States approximately 100,000 workers are exposed to these chemical compounds in the workplace each year and **5-10% of these workers will develop occupational asthma**. [Emphasis added.]

The 2000 Petsonk et al. paper,⁸ now 19 years old, did not indicate the ranking of diisocyanates with other causes of occupational asthma. It indicated a “low prevalence” where exposures are controlled:

Diisocyanates, a group of highly reactive chemicals, have been frequently associated with the new onset of asthma in relation to work exposures, although in industrial settings in which exposures to these chemicals are well controlled, **a low prevalence of symptoms has been reported**. [Emphasis added.]

⁶ The citation is Vandenplas O, Malo JL, Saetta M, Mapp CE, Fabbri LM. 1993. Occupational asthma and extrinsic alveolitis due to isocyanates; current status and perspectives. Br J Ind Med 50:213-228.

⁷ The citation is Bernstein, JA. 1996. Overview of diisocyanate occupational asthma. Toxicology 111(1-3):181-189.

⁸ The citation is Petsonk EL, Wang ML, Lewis DM, Siegel PD, Husberg BJ. 2000. Asthma-like symptoms in wood product plant workers exposed to methylene diphenyl diisocyanate. Chest 118:1183-1193.

The 2001 Wisnewski and Redlich paper,⁹ now 18 years old, referenced 11 papers in stating, “Diisocyanates are one of the most commonly identified causes of occupational asthma.” However, only one of the references, a 1999 paper by Jajosky et al.¹⁰ (now 20 years old), actually ranked the causes. Using data from 1993-1995 (24 to 26 years ago), it listed TDI as number 8 (3.7% of cases); diisocyanates NOS as number 10 (3.3% of cases); and MDI as number 15 (2.4% of cases).

The Wisnewski and Redlich paper estimated prevalence of isocyanate-caused occupational asthma at between 5 and 15%, citing earlier papers.

The 2002 Diller paper¹¹ (now 17 years old) did not refer to isocyanates as the leading cause of occupational asthma. Instead, in referencing a 1993 book (now 26 years old), it said:

In recent years, occupational asthma (OA) has become the most frequent occupational lung disease in many countries. Among the many agents that may cause OA, the isocyanates have gained wide attention.

The Diller paper indicated that incidence of TDI-caused occupational asthma was between 0 and 10% as of 2002:

Prevalence of occupational asthma due to toluene diisocyanate can be estimated from 10 cross-sectional studies, based on 788 persons. Prevalence had repeatedly been above 10 percent before 1985, and have been mostly between zero and 10 percent in recent years.

It added:

According to general surveillance schemes, compensation statistics, and disease registers, the annual case numbers of OA due to all types of isocyanates also show a downward trend in most countries during recent years, in spite of steadily increasing production and use of all isocyanates.

In short, the sources cited in the 2003 Ott et al. paper and the 2004 Bello et al. paper do not support the assertions that EPA has repeatedly made.

⁹ The citation is Wisnewski AV, Redlich CA. 2001. Recent developments in diisocyanate asthma. *Curr Opin Allergy Clin Immunol* 1:169-175.

¹⁰ The citation is Jajosky RA, Harrison R, Reinisch F, et al. Surveillance of work-related asthma in selected US states using surveillance guidelines for state health departments ± California, Massachusetts, Michigan, and New Jersey, 1993-1995. *Morb Mortal Weekly Rep CDC Surveillance Summaries* 1999; 48:1-20.

¹¹ The citation is Diller WF. 2002. Frequency and trends of occupational asthma due to toluene diisocyanate: A critical review. *Appl Occup Environ Hyg* 17:872-877.

c. **Tarlo et al. (1997)**

The 2006 NIOSH Alert cited only Tarlo et al.¹² for its assertion that “isocyanates are the leading attributable chemical cause of occupational asthma in the United States and many other industrialized countries.” This 1997 article appeared 22 years ago. While ACC has not reviewed the full article, its abstract reports that the paper “provides some evidence that facilities having OA claims have higher isocyanate exposures than to those without claims.” This suggests that any statement about isocyanates being the leading attributable chemical cause of occupational asthma was supported only by references to even earlier papers, as was the case with the Ott et al. paper and the Bello et al. paper. These papers relied on evidence now more than two decades old. They do not reflect current incidence rates, as demonstrated below.

Notably, much more recently, Tarlo has co-authored two articles that reported substantial declines in the isocyanate-related occupational asthma cases. The 2011 article¹³ found:

In conclusion, the study suggests that there has been a reduction in absolute number of ISO and N-ISO OA allowed claims, with a somewhat greater relative decline of ISO OA claims.

The 2016 article¹⁴ stated:

The recent period included a significantly smaller proportion (of OA cases) employed in the manufacturing industry and isocyanate-induced cases compared with the earlier period.

It established that there have only been 3 cases of diisocyanate-related occupational asthma in the years 2010-2014 in Toronto, Canada.

Thus, EPA should not continue to rely on a 2006 NIOSH alert that cites a 22-year-old paper whose lead author has since written at least twice on the substantial decline in the incidence of isocyanate-related occupational asthma.

3. Current Information Shows That Isocyanates Are Not a Significant Cause of Occupational Asthma

The outdated references on which EPA relies for its misleading statements about isocyanates and occupational asthma do not reflect the sharp drop in incidence of isocyanate-related occupational asthma. Current information establishes that isocyanates are now a minor cause of occupational asthma.

¹² The citation is Tarlo SM, Liss GM, Dias C, Banks DE. 1997. Assessment of the relationship between isocyanate exposure levels and occupational asthma. *Am J Ind Mem* 32(5):517-5 21.

¹³ The citation is Buyantseva L, Liss GM, Ribeiro, Manno M, Luce CE, Tarlo SM. 2011. Reduction in Diisocyanate and Non-Diisocyanate Sensitizer-Induced Occupational Asthma in Ontario. *JOEM*. DOI: 10.1097/JOM.0b013e3182122376.

¹⁴ The citation is Gotzev G, Lipszyc JC, Connor D, Tarlo SM. 2016. Trends in Occupations and Work Sectors Among Patients With Work-Related Asthma at a Canadian Tertiary Care Clinic. *Chest*. 150(4):811-818.

The NIOSH website reports on most-frequently reported causes of occupational asthma for the period of 2009-2012 in four states. The leading cause was reported to be “miscellaneous chemicals and materials” (not including isocyanates), accounting for 22.4% of the cases. Isocyanates were the 19th most-frequently reported cause, accounting for just 1.0% of the cases. This information contradicts the assertion in the 2006 NIOSH Alert.

A 2017 paper by Collins et al.¹⁵ reported that “diisocyanates, such as toluene diisocyanate (TDI), are a cause of occupational asthma.” It then explains that incidence rates for TDI-induced asthma have declined:

There is evidence from surveillance reports of declining trends in occupational asthma during the 1990s in the United States, United Kingdom, Finland, and Canada. Reviews of workplace studies indicate also that incidence rates of TDI-induced asthma have declined. These favorable trends appear to be related to a reduction in workplace exposures through engineering controls and changes in work practices.

A 2015 paper by Stocks¹⁶ et al. made its own finding about declining incidence rates:

From 2006 to 2014, there was a significant decline in the number of urine samples with detectable levels of [a biomarker for exposure to 1,6-hexamethylene diisocyanate (HDI)] Over the same period, there was a significant decline in all asthma cases attributed to isocyanates or spray painting reported to SWORD ... and a non-significant decline among MVR workers

This paper attributed the decline to improved industrial hygiene methods:

The simultaneous decrease in HDI exposure and incident cases of asthma reported to SWORD is temporally consistent with a reduction in exposure to airborne isocyanate leading to a reduction in asthma. Although this is not direct evidence of a causal relationship between the two trends, it is suggestive.

Declines were noted even in papers from a decade earlier. As noted above, the 2003 Ott et al. paper reported:

In the early years of the industry, annual incidence rates of occupational asthma (OA) due to TDI ranged from 1% to as high as 6%, depending on the extent of engineering and work practice controls in the various workplaces. Since the mid-1970s, annual OA incidence rates have been < 1%, where 8 h TDI concentrations have been maintained below 5 ppb as determined by personal monitoring, even where short-term TDI concentrations above 20 ppb and less frequently above 40 ppb were routinely detected.

¹⁵ The citation is Collins JJ, Anteau S, Conner PR, Cassidy LD, Doney B, Wang ML, Kurth L, Carson M, Molenaar D, Redlich CA, Storey E. 2017. Incidence of Occupational Asthma and Exposure to Toluene Diisocyanate in the United States Toluene Diisocyanate Production Industry. JOEM 59(125):S22-S27.

¹⁶ The citation is Stocks SJ, Jones K, Piney M, Agius RM. 2015. Isocyanate exposure and asthma in the UK vehicle repair industry. Occupational Medicine 2015;65:713-718.

In addition to improved industrial hygiene practices, substitution of MDI for TDI may also have contributed to the decline in incidence of isocyanate-related asthma. A 2005 paper by Krone et al.¹⁷ noted:

Prior to 1980, most PUF [polyurethane foam] was produced using toluene diisocyanate (TDI). Post-1980, there was a shift to the use of methylenediphenyl diisocyanate (MDI) and pre-polymers of TDI (pre-reacted TDI polymer) MDI was introduced as a safer substitute for TDI in the manufacture of PU due to MDI's exceedingly low volatility¹⁸ and correspondingly low inhalation potential (less than 1 ppb on average).

Recent data compiled by ACC show a consistent picture of a decline in asthma rates associated with diisocyanates over the last decade, even as production rates of diisocyanates have increased. The reduction in diisocyanate-related occupational asthma is primarily due to a variety of product stewardship activities, including education and training, enhanced worker awareness, improved work practices, use of less volatile diisocyanate forms (e.g., pre-polymers), improved engineering controls (e.g., containment and/or ventilation), better medical surveillance programs, minimization of peak exposures, and continuing emphasis on compliance with existing exposure standards. These product stewardship efforts are key to further reductions in cases.

Conclusion

EPA's repeated statements about isocyanates being the leading cause of occupational asthma and incidence rates of isocyanate-related asthma as high as 20% are inaccurate and based on assessments primarily from the 1990s and earlier. They do not reflect changes in industrial hygiene practices and switching from TDI to MDI in many applications. Current evidence indicates that isocyanates are not a leading cause of occupational asthma. They account for 1% or less of occupational asthma cases.

Accordingly, EPA should stop repeating those statements. Instead, it should review current scientific literature. It should make its regulatory decisions under section 5 in light of current information, not on the basis of outdated and inaccurate papers.

¹⁷ The citation is Krone CA, Klinger TD. 2005. Isocyanates, polyurethane and childhood asthma. *Pediatric Allergy Immunol* 2005;16:368-379.

¹⁸ TDI has a vapor pressure of 0.01 mm Hg, whereas MDI has a vapor pressure of 0.000005 mm Hg, four orders of magnitude lower. See the NIOSH Pocket Guide to Chemical Hazards.

AMERICAN CHEMISTRY COUNCIL ENVIRONMENTAL PROTECTION AGENCY MEETING AGENDA

Date: Wednesday, April 10, 2019
Time: 8:00 – 9:00 am Eastern
Location: EPA East Building
 1200 Constitution Avenue, NW
 Washington, DC 20004

Time	Topic	Lead
8:00 a.m.	Administrative <ul style="list-style-type: none"> • Introductions • Background • Purpose of Meeting 	S. Osman-Sypher, ACC C. Franz, ACC
8:10 a.m.	Discuss ACC Questions on EPA's Approach to Isocyanate-Based Polymers Under Section 5 of TSCA	S. Osman-Sypher, ACC C. Franz, ACC
8:50 a.m.	Discuss Next Steps	S. Osman-Sypher, ACC C. Franz, ACC
9:00 a.m.	Adjournment	

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist, a part of ACC's Antitrust Compliance Guide, is for use by ACC staff and member company representatives in the conduct of ACC-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to ACC-sponsored meetings. The checklist is not exhaustive and does not address antitrust issues relating to activities other than ACC meetings. Participants in ACC meetings also should be thoroughly familiar with the Antitrust Compliance Guide.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- Have an ACC staff representative at each ACC-sponsored meeting;
- Consult with ACC counsel on all antitrust questions relating to ACC-sponsored meetings;
- Limit meeting discussions to agenda topics (unless additional topics have been approved by the ACC staff representative); and
- Provide each member company representative and ACC employee attending an ACC-sponsored meeting with a copy of this checklist, and have a copy available for reference at all ACC-sponsored meetings.

RECORDKEEPING:

- Have an agenda and minutes which accurately reflect the matters which occur; and
- Provide agendas and minutes to ACC legal counsel for review and approval in advance of distribution.

VIGILANCE:

- Protest against or stop any discussion or meeting activities which appear to violate this checklist. Member company representatives should disassociate themselves from any such discussion or activities and leave any meeting in which they continue.

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- Individual company prices, price changes, price differentials, markups, discounts, allowance, credit terms, etc.;
- Individual company data on costs, production, capacity, inventories, sales, etc.; and
- Industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- Changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- Company bids on contracts for particular products; company procedures for responding to bid invitations; and
- Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Message

From: Bauer, Jeff [Bauer.Jeff@epa.gov]
Sent: 4/8/2020 3:03:12 PM
To: Berger, Tom C. [Berger@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]; Price, Amanda [price@khlaw.com]
Subject: RE: P-16-05X3

Tom,

I am having a engineering report run with inhalation exposure so that the HH assessor and I are working of the same exposure for worker inhalation exposure and fugitive air releases.

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: P-16-05X3

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: P-16-05X3

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: P-16-05X3

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Green Chemistry award winner LVEA (Lauren Davis) and P-16-05X3 (where I had hidden the integer “X”) with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a Green Chemistry award winner is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: P-16-05X3

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail

Ex. 5 Attorney Client (AC)

ess

both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spay test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW

Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Monday, November 18, 2019 1:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M

1201 Constitution Ave., NW

Washington, DC 20004

Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 7/17/2020 7:43:48 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just making sure you received this – please let us know if you also would like it submitted via CDX.

Best regards,
Tom

From: Berger, Tom C.
Sent: Wednesday, July 15, 2020 3:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

We are following up to our telephone conference call of July 1, 2020 concerning ongoing review of **Ex. 4 CBI**

Ex. 4 CBI Specifically, on behalf of the submitter, we are providing: **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful and that it addresses the Agency's concerns. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, June 29, 2020 12:13 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

And if there are any new or updated relevant Agency documents, please send them along to us before our call.

Thanks again - Tom

From: Berger, Tom C.

Sent: Thursday, June 18, 2020 4:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khilaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khilaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I received your placeholder invite for July 1 at 2:00 ET. I will circulate a MS Outlook invite with dial-in instructions for a call at that time.

Thanks again – Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Tuesday, June 16, 2020 8:50 AM

To: Berger, Tom C. <Berger@khilaw.com>

Cc: Price, Amanda <price@khilaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khilaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>

Subject: RE: **Ex. 4 CBI**

Tom,

How about I try and set it up for July 1st. in the afternoon.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khilaw.com>

Sent: Monday, June 15, 2020 4:05 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khilaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khilaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, June 9, 2020 12:53 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.

Sent: Thursday, June 4, 2020 10:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.

Sent: Monday, June 1, 2020 5:55 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and

- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.

Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Alwood, Jim <alwood.jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacturer could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, May 27, 2020 2:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, May 13, 2020 1:32 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments: **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test.

Ex. 4 CBI

Ex. 4 CBI

RAD has the

information and I am trying to get them to do the risk assessment based on

Ex. 4 CBI

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>

Sent: Tuesday, April 21, 2020 4:58 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Thursday, April 16, 2020 1:02 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg

<Schweer.Greg@epa.gov>

Subject: RE: Ex. 4 CBI

Tom,

The chemist sent me a memo (Ex. 4 CBI) and they had two questions, I called and left you a message today (Ex. 4 CBI) I sent RAD a request last week to update the HH assessment (Ex. 4 CBI) as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.

Sent: Friday, March 6, 2020 1:33 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.

Sent: Tuesday, February 25, 2020 9:08 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Thursday, February 20, 2020 12:18 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

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From: Berger, Tom C.

Sent: Monday, November 18, 2019 1:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff

Sent: Tuesday, March 26, 2019 11:37 AM

To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, March 26, 2019 11:30 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: Ex. 4 CBI

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 4/8/2020 2:47:30 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]; Bauer, Jeff [Bauer.Jeff@epa.gov]; Price, Amanda [price@khlaw.com]
Subject: RE: P-16-05X3

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: P-16-05X3

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: P-16-05X3

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Green Chemistry award winner LVEA (Lauren Davis) and P-16-05X3 (where I had hidden the integer “X”) with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a Green Chemistry award winner is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: P-16-05X3

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail

st
q
b

Ex. 5 Attorney Client (AC)

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Monday, January 13, 2020 2:50 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,

Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spay test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 7/15/2020 7:53:06 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi Jeff --

I hope that all is well.

We are following up to our telephone conference call of July 1, 2020 concerning ongoing review of **Ex. 4 CBI**
Ex. 4 CBI Specifically, on behalf of the submitter, we are providing: **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful and that it addresses the Agency's concerns. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, June 29, 2020 12:13 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: Ex. 4 CBI

And if there are any new or updated relevant Agency documents, please send them along to us before our call.

Thanks again - Tom

From: Berger, Tom C.
Sent: Thursday, June 18, 2020 4:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I received your placeholder invite for July 1 at 2:00 ET. I will circulate a MS Outlook invite with dial-in instructions for a call at that time.

Thanks again – Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, June 16, 2020 8:50 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

How about I try and set it up for July 1st. in the afternoon.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, June 15, 2020 4:05 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, June 9, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.

Sent: Thursday, June 4, 2020 10:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.

Sent: Monday, June 1, 2020 5:55 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.

Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA "automatically" seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the "new use" being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, May 27, 2020 2:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.

Sent: Friday, May 8, 2020 11:14 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.

Sent: Thursday, May 7, 2020 4:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" or **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the
information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

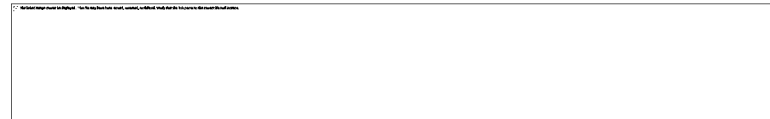
Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Thursday, April 16, 2020 1:02 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo d **Ex. 4 CBI** t and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager

ED_005294A_00000617-00012

United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a **Ex. 4 CBI** **Ex. 4 CBI** is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use [Ex. 4 CBI]s as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: [Ex. 4 CBI]

Tom, I am expecting information from the engineer today or tomorrow on the s [Ex. 4 CBI] test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: [Ex. 4 CBI]

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/29/2020 4:13:23 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

And if there are any new or updated relevant Agency documents, please send them along to us before our call.

Thanks again - Tom

From: Berger, Tom C.
Sent: Thursday, June 18, 2020 4:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I received your placeholder invite for July 1 at 2:00 ET. I will circulate a MS Outlook invite with dial-in instructions for a call at that time.

Thanks again – Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, June 16, 2020 8:50 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

How about I try and set it up for July 1st. in the afternoon.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, June 15, 2020 4:05 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, June 9, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.
Sent: Thursday, June 4, 2020 10:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.
Sent: Monday, June 1, 2020 5:55 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth'

<Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.

Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, May 27, 2020 2:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, May 13, 2020 1:32 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Wednesday, May 13, 2020 12:53 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.

Sent: Friday, May 8, 2020 11:14 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.

Sent: Thursday, May 7, 2020 4:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
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From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, May 07, 2020 1:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, May 5, 2020 11:56 AM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, April 29, 2020 11:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
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tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI. RAD has the information and I am trying to get them to do the risk assessment based on Ex. 4 CBI

Jeff Bauer - Program Manager
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From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the Ex. 4 CBI case, we understand that the chemist has two questions concerning Ex. 4 CBI

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Tom,

The chemist sent me a memo Ex. 4 CBI and they had two questions, I called and left you a message today Ex. 4 CBI I sent RAD a request last week to update the HH assessment Ex. 4 CBI as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
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New Chemicals Program (7405M)
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.

Sent: Monday, March 30, 2020 3:46 PM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

Subject: RE: Ex. 4 CBI

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Monday, March 30, 2020 3:42 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>

Subject: RE: P-16-05X3

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Monday, March 30, 2020 11:51 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.

Sent: Tuesday, March 24, 2020 11:12 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a **Ex. 4 CBI** is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don’t want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, January 07, 2020 4:16 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

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Message

From: Sullivan, Andrew [sullivan.andrew@epa.gov]
Sent: 6/19/2020 12:25:38 PM
To: Price, Amanda [price@khlaw.com]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]
Subject: RE: Another Redacted Report RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

Thanks for your reply.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

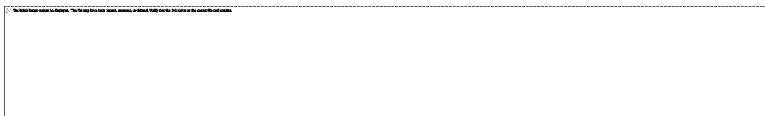
From: Price, Amanda <price@khlaw.com>
Sent: Thursday, June 18, 2020 4:13 PM
To: Sullivan, Andrew <sullivan.andrew@epa.gov>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Another Redacted Report RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

We received the report and are able to access it.

Thank you,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>

Sent: Thursday, June 18, 2020 11:46 AM

To: Price, Amanda <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>

Subject: [Not Virus Scanned] Another Redacted Report RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

I have attached the password protected Third Party Sanitized Reports you requested and that we talked about recently. I will send you the password to access the report in a separate email. Please reply that you've received them and have been able to access the report. Thank you!

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Sullivan, Andrew

Sent: Wednesday, May 6, 2020 3:54 PM

To: 'Price, Amanda' <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Great Amanda, Thanks for confirming.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Price, Amanda <price@khlaw.com>

Sent: Wednesday, May 6, 2020 3:41 PM

To: Sullivan, Andrew <sullivan.andrew@epa.gov>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

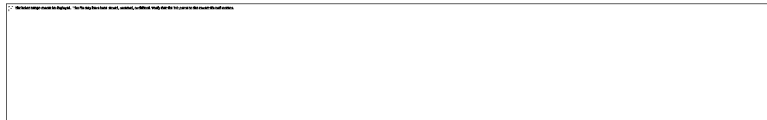
We received the two reports and are able to open them.

Thank you,

Amanda (Mandy) C. Price
Scientific Assistant

KELLER AND HECKMAN LLP

tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>

Sent: Wednesday, May 6, 2020 2:05 PM

To: Price, Amanda <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>

Subject: [Not Virus Scanned] RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda and Tom,

Thank you for returning the signed authorization form. I confirmed that Tom is listed as a technical contact on your cases and have attached the password protected Third Party Sanitized Reports you requested.

Please reply that you've received them and have been able to access the reports. I will send you the passwords to access these files in a separate email.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Price, Amanda <price@khlaw.com>
Sent: Wednesday, May 6, 2020 1:36 PM
To: Sullivan, Andrew <sullivan.andrew@epa.gov>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

Attached is the authorization form you requested. We look forward to receiving the reports.

Best regards,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>
Sent: Wednesday, May 6, 2020 8:53 AM
To: Price, Amanda <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>
Subject: FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Good Morning Amanda,

I didn't received the authorization form from you yet so I am forwarding my earlier request for you to fill out and sign the authorization form allowing EPA to email you third party redacted reports. Thank you.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605

From: Sullivan, Andrew <sullivan.andrew@epa.gov>

Sent: Wednesday, April 29, 2020 3:20 PM

To: Price, Amanda <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>

Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

As we discussed, please add the 2 LVE case numbers that I am working on with you to the attached authorization form, sign it, and email it back (reply all). Then I can email you the redacted reports we discussed earlier. Here is the formal authorization request. Thank you.

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact

Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case, Drew Sullivan, at the number below.

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/18/2020 8:21:31 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I received your placeholder invite for July 1 at 2:00 ET. I will circulate a MS Outlook invite with dial-in instructions for a call at that time.

Thanks again – Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, June 16, 2020 8:50 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

How about I try and set it up for July 1st. in the afternoon.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, June 15, 2020 4:05 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, June 9, 2020 12:53 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.

Sent: Thursday, June 4, 2020 10:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.

Sent: Monday, June 1, 2020 5:55 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and

- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.

Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Alwood, Jim <alwood.jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNURs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, May 27, 2020 2:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, May 13, 2020 1:32 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. Ex. 4 CBI

Ex. 4 CBI

information and I am trying to get them to do the risk assessment based on . RAD has the
Ex. 4 CBI

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg

<Schweer.Greg@epa.gov>

Subject: RE: Ex. 4 CBI

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a Ex. 4 CBI is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.

Sent: Friday, March 6, 2020 1:33 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.

Sent: Tuesday, February 25, 2020 9:08 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Thursday, February 20, 2020 12:18 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.

Sent: Monday, November 18, 2019 1:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff

Sent: Tuesday, March 26, 2019 11:37 AM

To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, March 26, 2019 11:30 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: French, Lee [lee.french@dupont.com]
Sent: 4/1/2020 2:06:28 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]; Castorano, Michael [michael.castorano-1@dupont.com]
CC: Hundal, Amrit [Hundal.Amrit@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: Authorization Form - Signed.docx

Hi Greg,

In the interest of expediting the completion of the submission review we authorize the use of email to transmit the materials needed to finalize review process.

Signed waiver is attached.

Regards,

Lee French
PS&R TSCA Consultant
1801 Larkin Center Dr.,
Larkin Lab; Office 351
Midland, MI 48642



Lee.French@dupont.com
www.dupont.com

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 31, 2020 12:35 PM
To: French, Lee <lee.french@dupont.com>; Castorano, Michael <michael.castorano-1@dupont.com>
Cc: Hundal, Amrit <Hundal.Amrit@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: [EXTERNAL] Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Lee and Michael,

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 3, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement, EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e).

Please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

This communication is for use by the intended recipient and contains information that may be Privileged, confidential or copyrighted under applicable law. If you are not the intended recipient, you are hereby formally notified that any use, copying or distribution of this e-mail, in whole or in part, is strictly prohibited. Please notify the sender by return e-mail and delete this e-mail from your system. Unless explicitly and conspicuously designated as "E-Contract Intended", this e-mail does not constitute a contract offer, a contract amendment, or an acceptance of a contract offer. This e-mail does not constitute a consent to the use of sender's contact information for direct marketing purposes or for transfers of data to third parties.

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Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: **Ex. 4 CBI**

DuPont Specialty Products USA, LLC authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to DuPont Specialty Products USA, LLC through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on **Ex. 4 CBI** are teleworking due to COVID-19 concerns and may be withdrawn at any time.

I have the authority to sign this on behalf of DuPont Specialty Products USA, LLC

Ex. 6 Personal Privacy (PP)

Signature of authorized person: _____
Name of authorized person printed or typed: Lee French
Title: TSCA consultant
Email address: Lee.French@DuPont.com
Telephone number: 989.859.6248
DuPont Specialty Products USA, LLC

Message

From: Price, Amanda [price@khlaw.com]
Sent: 6/18/2020 8:13:16 PM
To: Sullivan, Andrew [sullivan.andrew@epa.gov]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]
Subject: RE: Another Redacted Report RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: ATT00001.txt

Dear Drew,

We received the report and are able to access it.

Thank you,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>
Sent: Thursday, June 18, 2020 11:46 AM
To: Price, Amanda <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>
Subject: [Not Virus Scanned] Another Redacted Report RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

I have attached the password protected Third Party Sanitized Reports you requested and that we talked about recently. I will send you the password to access the report in a separate email. Please reply that you've received them and have been able to access the report. Thank you!

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics

Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Sullivan, Andrew
Sent: Wednesday, May 6, 2020 3:54 PM
To: 'Price, Amanda' <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Great Amanda, Thanks for confirming.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Price, Amanda <price@khlaw.com>
Sent: Wednesday, May 6, 2020 3:41 PM
To: Sullivan, Andrew <sullivan.andrew@epa.gov>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

We received the two reports and are able to open them.

Thank you,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>

Sent: Wednesday, May 6, 2020 2:05 PM

To: Price, Amanda <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>

Subject: [Not Virus Scanned] RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda and Tom,

Thank you for returning the signed authorization form. I confirmed that Tom is listed as a technical contact on your cases and have attached the password protected Third Party Sanitized Reports you requested.

Please reply that you've received them and have been able to access the reports. I will send you the passwords to access these files in a separate email.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Price, Amanda <price@khlaw.com>

Sent: Wednesday, May 6, 2020 1:36 PM

To: Sullivan, Andrew <sullivan.andrew@epa.gov>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

Attached is the authorization form you requested. We look forward to receiving the reports.

Best regards,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP

tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>
Sent: Wednesday, May 6, 2020 8:53 AM
To: Price, Amanda <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>
Subject: FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Good Morning Amanda,

I didn't received the authorization form from you yet so I am forwarding my earlier request for you to fill out and sign the authorization form allowing EPA to email you third party redacted reports. Thank you.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Sullivan, Andrew <sullivan.andrew@epa.gov>
Sent: Wednesday, April 29, 2020 3:20 PM
To: Price, Amanda <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>
Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

As we discussed, please add the 2 LVE case numbers that I am working on with you to the attached authorization form, sign it, and email it back (reply all). Then I can email you the redacted reports we discussed earlier. Here is the formal authorization request. Thank you.

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking

from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. Also please follow the instructions below for the transmittal of information subject to this agreement. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case, Drew Sullivan, at the number below.

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490

DO NOT SEND CBI TO THIS EMAIL

Message

From: Sullivan, Andrew [sullivan.andrew@epa.gov]
Sent: 6/18/2020 3:45:44 PM
To: Price, Amanda [price@khlaw.com]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Yan, James [Yan.James@epa.gov]; Berger, Tom C. [Berger@khlaw.com]; Sullivan, Andrew [sullivan.andrew@epa.gov]
Subject: Another Redacted Report RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: L-20-XXXX-XXXX_HLTH Risk Assessment FINAL_Third Party Sanitized_Marked AMS DTS_Redacted.pdf

Hello Amanda,

I have attached the password protected Third Party Sanitized Reports you requested and that we talked about recently. I will send you the password to access the report in a separate email. Please reply that you've received them and have been able to access the report. Thank you!

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Sullivan, Andrew
Sent: Wednesday, May 6, 2020 3:54 PM
To: 'Price, Amanda' <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Great Amanda, Thanks for confirming.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

From: Price, Amanda <price@khlaw.com>
Sent: Wednesday, May 6, 2020 3:41 PM

To: Sullivan, Andrew <sullivan.andrew@epa.gov>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

We received the two reports and are able to open them.

Thank you,

Amanda (Mandy) C. Price

Scientific Assistant

KELLER AND HECKMAN LLP

tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com

1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>

Sent: Wednesday, May 6, 2020 2:05 PM

To: Price, Amanda <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Sullivan, Andrew <sullivan.andrew@epa.gov>

Subject: [Not Virus Scanned] RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda and Tom,

Thank you for returning the signed authorization form. I confirmed that Tom is listed as a technical contact on your cases and have attached the password protected Third Party Sanitized Reports you requested.

Please reply that you've received them and have been able to access the reports. I will send you the passwords to access these files in a separate email.

Best,

Andrew (Drew) Sullivan | Program Manager

New Chemicals Management Branch

Chemical Control Division

U.S. EPA Office of Pollution Prevention and Toxics

Phone: 202-564-0605

Fax: 202-564-9490

DO NOT SEND CBI TO THIS EMAIL

From: Price, Amanda <price@khlaw.com>
Sent: Wednesday, May 6, 2020 1:36 PM
To: Sullivan, Andrew <sullivan.andrew@epa.gov>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Drew,

Attached is the authorization form you requested. We look forward to receiving the reports.

Best regards,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Sullivan, Andrew <sullivan.andrew@epa.gov>
Sent: Wednesday, May 6, 2020 8:53 AM
To: Price, Amanda <price@khlaw.com>
Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>
Subject: FW: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Good Morning Amanda,

I didn't received the authorization form from you yet so I am forwarding my earlier request for you to fill out and sign the authorization form allowing EPA to email you third party redacted reports. Thank you.

Best,

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics

From: Sullivan, Andrew <sullivan.andrew@epa.gov>

Sent: Wednesday, April 29, 2020 3:20 PM

To: Price, Amanda <price@khlaw.com>

Cc: Schweer, Greg <Schweer.Greg@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>; Yan, James <Yan.James@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>

Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Hello Amanda,

As we discussed, please add the 2 LVE case numbers that I am working on with you to the attached authorization form, sign it, and email it back (reply all). Then I can email you the redacted reports we discussed earlier. Here is the formal authorization request. Thank you.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Andrew (Drew) Sullivan | Program Manager
New Chemicals Management Branch
Chemical Control Division
U.S. EPA Office of Pollution Prevention and Toxics
Phone: 202-564-0605
Fax: 202-564-9490
DO NOT SEND CBI TO THIS EMAIL

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/30/2020 7:46:26 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]; Bauer, Jeff [Bauer.Jeff@epa.gov]; Price, Amanda [price@khlaw.com]
Subject: RE: P-16-05X3

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: P-16-05X3

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Green Chemistry award winner LVEA (Lauren Davis) and P-16-05X3 (where I had hidden the integer “X”) with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a Green Chemistry award winner is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: P-16-05X3

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail

Ex. 5 Attorney Client (AC)

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spray test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me

bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.Jeff@Epa.gov' <Bauer.Jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/16/2020 7:49:41 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

Jeff – that works for us. Once you select the precise time on 7/1, would you like to send the meeting invite with dial-in instructions, or should I (I would be happy to)?

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, June 16, 2020 8:50 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

How about I try and set it up for July 1st. in the afternoon.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, June 15, 2020 4:05 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, June 9, 2020 12:53 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.

Sent: Thursday, June 4, 2020 10:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.

Sent: Monday, June 1, 2020 5:55 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.
Sent: Thursday, May 28, 2020 12:23 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, May 27, 2020 2:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address your questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI**, but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo [Ex. 4 CBI] and they had two questions, I called and left you a message today [Ex. 4 CBI] I sent RAD a request last week to update the HH assessment [Ex. 4 CBI] as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: [Ex. 4 CBI]

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: [Ex. 4 CBI]

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis where a **Ex. 4 CBI** is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
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From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

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Thanks again - Tom

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Cc: Daniels, Rhys G. <daniels@khlaw.com>
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The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
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This is becoming more urgent from a commercial standpoint.

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Thomas C. Berger

Partner

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Message

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Sent: 3/30/2020 3:51:09 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: P-16-05X3

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Green Chemistry award winner LVEA (Lauren Davis) and P-16-05X3 (where I had hidden the integer “X”) with Jeff Bauer.

Thanks all always - Tom

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Ex. 5 Attorney Client (AC)

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Is there any update?

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Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
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Ex. 5 Deliberative Process (DP)

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From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/24/2020 2:48:22 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]
Subject: FW: P-16-05X3

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more

Ex. 5 Attorney Client (AC)

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

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tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use in spray applications as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I am expecting information from the engineer today or tomorrow on the spray test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 2/12/2020 12:51:01 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]
Subject: RE: PMN backlog

Greg – thank you so much.

Also – **Ex. 6 Personal Privacy (PP)**

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Wednesday, February 12, 2020 5:38 AM
To: Berger, Tom C. <Berger@khlaw.com>
Subject: Re: PMN backlog

Tom,

This is the best I can do at present. You do not need to attribute this to me.

On our webpage titled “Statistics for the New Chemicals Review Program under TSCA” (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#stats>), we provide statistics on the active cases under review. The statistics as of 2/1/2020 were posted recently and show the active number of cases down from 352 on 1/1/2020 to 303 cases on 2/1/2020. Of these 303 cases, approximately 38 cases were in the risk assessment phase, 93 cases were in the risk characterization phase, 122 cases were awaiting additional information from the submitter, 30 cases were in the regulatory decision and action development stage, and 20 cases were awaiting the submitter signature for an Order.” We were able to complete a substantial number of cases in January and we continue to actively work to reduce the backlog of PMN submissions that have been under review for over 90 days.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, February 11, 2020 9:12 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Subject: Re: PMN backlog

Anything I could get by noon Wednesday would be helpful but of course understand if you can’t respond.

Thanks as always - Tom

On Feb 11, 2020, at 9:57 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

I hope that all is well!

During Keller and Heckman's next monthly "30/30" webinar, which is tomorrow, I will be talking about how the regulated community should not be afraid of the PMN section 5 process. I was going to mention faster reviews and reduced PMN backlog. Can you give me any very general information/stats on these topics? The last figures I have are from last October ("278 PMNs"). I will or will not give attribution for any information you provide as you indicate.

Thanks much –

Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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